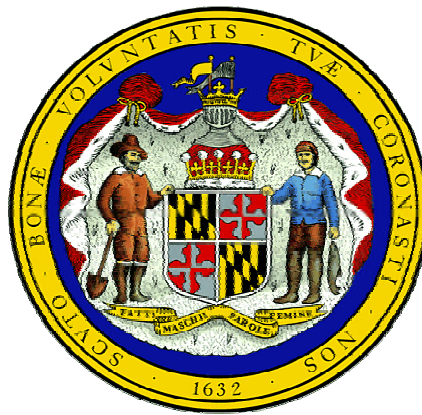


An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services



MARYLAND HEALTH CARE COMMISSION

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I. INTRODUCTION

A. *Purpose of the Working Paper*

Through House Bill 995¹, the General Assembly required the Maryland Health Care Commission (MHCC or the Commission) to examine major policy issues of the Certificate of Need (CON) process. In January 2000, the MHCC submitted a report to the General Assembly that provided a detailed work plan for studying the CON process in Maryland. This work plan identified specific services for in-depth study over a two-year period (Calendar Years 2000 and 2001). During the first year of the study, the MHCC analyzed and evaluated CON regulation in Maryland for five services that included: (1) acute inpatient obstetric services, (2) cardiac surgery and therapeutic catheterization services, (3) home health services, (4) hospice services, and (5) nursing home services. A final report providing the Commission's recommendations on these services was submitted to the General Assembly in January 2001.²

This paper is part of the series of working papers that the MHCC is releasing during the second phase of the two-year study period. (Working papers regarding rehabilitation and chronic hospital services, adult inpatient psychiatry services, acute inpatient services, substance abuse services, and ambulatory surgery services were released by the MHCC between May and September 2001.) Under § 19-123(j) of the Health-General Article, a Certificate of Need is required before a health care facility establishes an open heart surgery, organ transplant surgery, neonatal intensive care service, or burn service. Specifically, this report examines policy and regulatory issues affecting the last three of those specialized health care services. It also outlines several alternative options for changes to the CON program and their potential implications.

B. *Invitation for Public Comment*

The Commission invites all interested organizations and individuals to submit comments on the options presented in this working paper. Written comments should be submitted no later than the close of business Friday, November 16, 2001 to:

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¹ Chapter 702, Acts of 1999.

² Maryland Health Care Commission, *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Phase I Final Report to the Maryland General Assembly*, January 1, 2001.

C. Organization of the Working Paper

This paper is organized into six sections. Following this Introduction, Part II of the paper is divided into three sub-sections, containing overviews of organ transplant services, neonatal intensive care services, and burn services, including definitions of those services, inventories of existing providers, and data on utilization trends. These sub-sections also discuss alternatives to and trends in these services, and issues related to quality of care and access to care. Part III describes the functions of the federal and state government agencies with an interest in, or related to their authority over, activities in organ transplant surgery, neonatal intensive care services, and burn services. Part IV compares Maryland Certificate of Need regulation to what other states are doing with regard to regulating these three types of services. Part V of the paper, outlines alternative regulatory strategies for the Certificate of Need program for organ transplant services, neonatal intensive care services, and burn services that reflect different assumptions about the role of government regulatory agencies and the role of the market place in protecting the public interest. A summary table, illustrating the alternative options to CON regulation for these three services discussed in this working paper, is provided in Part VI.

II. OVERVIEW: MARYLAND ORGAN TRANSPLANT SURGERY, NEONATAL INTENSIVE CARE SERVICES, AND BURN SERVICES

A. *Introduction*

The Commission is given a specific mandate for identifying services to be regionalized under Maryland health planning law. The concept of health care regionalization refers to the appropriate distribution of services with regard to their geographic location and level of care. It implies an organized and integrated hierarchy of services with levels of care coordinated and mutually supportive. The most complex health problems are directed to tertiary care, the most technologically sophisticated component of the health care delivery system. Tertiary care interventions are provided to segments of the population that are the most severely ill and at the highest risk for poor outcomes. The diagnostic and therapeutic services provided at the tertiary care level are more advanced and the cost of staffing and equipping these specialized services is high. In this working paper, three of the highly specialized services that now require a Certificate of Need for establishment are reviewed: organ transplant surgery, neonatal intensive care unit (NICU), and burn care services.

B. *Organ Transplant Surgery*

1. *Definition*

Under Maryland health planning law, the establishment of organ transplant services requires CON approval. To guide the review of proposed new services and the development of any needed new capacity, the Commission's State Health Plan (SHP) contains planning policies, a need projection, and criteria and standards. COMAR 10.24.15.04B(1) defines the types of transplant programs for which a Certificate of Need is required. For purposes of CON regulation, organ transplantation refers to the major solid organs (kidney, liver, pancreas, heart and lung), intestine or small bowel, hematopoietic stem cells, and other transplantable cells.

Organ transplant programs are classified in the SHP as Solid Organ Transplant Programs, Hematopoietic Stem Cell Transplant Programs, or programs that focus on other transplantable cells. Based on donor types, there are two primary types of stem cell transplantation: (1) autologous transplants or (2) allogeneic transplants. An autologous transplant pertains to a transplant where the patient donates his own stem cells while an allogeneic transplant refers to a transplant where a second party donor is required. The following table provides a more specific breakdown of the categories of covered transplant programs.

Table 1
Categories of Covered Transplant Programs

Program	Organ Type
Solid Organ Programs	Kidney Liver Pancreas Heart Lung Heart/Lung Intestine (Small Bowel) Others, to be determined by the Commission as needed
Hematopoietic Stem Cell (Bone marrow) Programs	Autologous Allogeneic
Other Transplantable Cells	Islet Cells Hepatocytes Others, to be determined by the Commission as needed

Source: Maryland Health Care Commission

2. Supply and Distribution of Organ Transplant Programs

Since organ transplantation is a specialized health service appropriate for regional planning, two regional service areas are designated in the SHP. These regions are consistent with the service areas of the two federally designated Organ Procurement Organizations serving Maryland. The Transplant Resource Center of Maryland (TRC) serves western and central Maryland, the Eastern Shore, and Calvert and St. Mary's counties in the southern Maryland area. The Washington Regional Transplant Consortium (WRTC) serves Washington, D.C., Montgomery, Prince George's, and Charles Counties in Maryland, and Northern Virginia. TRC and WRTC, as well as Delaware, Pennsylvania, West Virginia, and New Jersey, are included in Region 2 of the United Network for Organ Sharing (UNOS), a private non-profit organization with responsibility for obtaining organs from donors and allocating and distributing organs to recipients.

Table 2 identifies the solid organ transplant programs in the Baltimore metropolitan region, which are served by TRC and the solid organ transplant programs in the Washington, D.C. metropolitan region, which are serviced by WRTC. The hematopoietic stem cell transplant programs in both regions are also included in the table.

Table 2
Transplant Center Location: Baltimore and Washington Metropolitan Regions

<p><u>Kidney Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital Johns Hopkins Bayview³ University of Maryland Medical Center</p> <p>Washington Metropolitan Region: Children's Hospital (DC) Georgetown University Hospital (DC) Howard University Hospital (DC) Walter Reed Army Medical Center (DC) Washington Hospital Center (DC) Fairfax Hospital (VA)</p>	<p><u>Heart Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital University of Maryland Hospital</p> <p>Washington Metropolitan Region: Children's Hospital (DC) Washington Hospital Center (DC) Fairfax Hospital (VA)</p>
<p><u>Liver Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital University of Maryland Hospital</p> <p>Washington Metropolitan Region: Howard University Hospital (DC) Fairfax Hospital (VA) Georgetown University Hospital</p>	<p><u>Lung Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital University of Maryland Hospital</p> <p>Washington Metropolitan Region: Fairfax Hospital (VA)</p>
<p><u>Pancreas Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital University of Maryland Hospital</p> <p>Washington Metropolitan Region: Georgetown University Hospital (DC) Walter Reed Army medical Center (DC) Washington Hospital Center (DC) Fairfax Hospital (VA)</p>	<p><u>Intestine, Small Bowel Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Johns Hopkins Hospital</p> <p>Washington Metropolitan Region: (None)</p>
<p><u>Hematopoietic Stem Cell Transplant Programs:</u></p> <p>Baltimore Metropolitan Region: Greater Baltimore Medical Center Johns Hopkins Hospital University of Maryland Hospital Sinai Hospital</p> <p>Washington Metropolitan Region: Children's Hospital (DC) Fairfax Hospital (VA) Georgetown University Hospital (DC) Holy Cross Hospital (MD) National Institutes of Health (MD) Walter Reed Army Medical Center (DC) Washington Hospital Center/George Washington(DC)</p>	<p><u>Islet Cells, Hepatocytes, etc.</u></p> <p>Baltimore Metropolitan Region: (None)</p> <p>Washington Metropolitan Region: (None)</p>

Source: Maryland Health Care Commission Note: Includes Federal Hospitals

³ Hopkins reports that it has consolidated its kidney transplant program to the Hopkins campus, although the Bayview campus is still Medicare certified as a kidney transplant center.

As of September 7, 2001, 260 medical institutions in the United States operate at least one organ transplant program.⁴ These transplant centers are categorized into organ specific programs that include the following active programs:

Table 3
Number and Type of Organ Transplant Programs: U.S., September 7, 2001

Type of Program	Number
Kidney Transplant	245
Liver Transplant	122
Pancreas Transplant	137
Pancreas Islet Cell Transplant	32
Intestine Transplant	39
Heart Transplant	141
Heart-Lung Transplant	82
Lung	76
Total	874

Source: UNOS, Critical Data, as of September 7, 2001

The following table shows total UNOS membership as well as kidney transplant membership, broken down into regions:

Table 4
UNOS Total Number of Centers and Kidney Transplant Programs: United States, 2001

Region	States	Total Number of Centers	Kidney Transplant Programs
1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	15	15
2	Delaware (1), District of Columbia (5), Maryland (3), New Jersey (6), Pennsylvania (16), West Virginia (2); Virginia (1)	33	33
3	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico	30	25
4	Oklahoma, Texas	34	30
5	Arizona, California, Nevada, New Mexico, Utah	36	35
6	Alaska, Hawaii, Idaho, Montana, Oregon, Washington	9	9
7	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin	21	21
8	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming	20	20
9	New York, Vermont	16	15
10	Indiana, Michigan, Ohio	23	20
11	Kentucky, North Carolina, South Carolina, Tennessee, Virginia (4)	23	22
TOTAL		260	245

Source: UNOS, Member Directory, as of September 14, 2001

Note: Total Programs (n=260), Kidney Programs (n=245) - Includes programs in federal facilities.

⁴ http://www.unos.org/Newsroom/critdata_main.htm

3. Trends in the Utilization of Organ Transplant Services

The number of solid organ transplants performed in the United States has increased by approximately 45 percent from 1990 to 1999. As shown in Table 5, intestine and pancreas transplants have experienced the greatest percentage increase over the ten-year period.

Table 5
Trends in the Utilization of Solid Organ Transplant Programs: United States, 1990-September 2000

Program	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000*
Kidney	9,416	9,674	9,737	10,357	10,644	11,048	11,360	11,676	12,365	12,493	9,738
Pancreas	69	78	64	113	94	107	164	208	245	362	314
Kidney-Pancreas	459	452	492	661	748	918	860	852	972	930	729
Liver	2,690	2,953	3,064	3,441	3,651	3,925	4,070	4,177	4,503	4,696	3,708
Heart	2,107	2,126	2,171	2,297	2,340	2,361	2,346	2,293	2,345	2,182	1,739
Lung	203	405	535	668	722	872	814	930	864	877	748
Heart-Lung	52	51	48	60	71	69	39	62	47	49	31
Intestine	5	12	22	34	23	45	45	68	68	70	53
Total	15,001	15,751	16,133	17,631	18,293	19,345	19,698	20,266	21,409	21,659	17,060

Data on intestine transplants was not collected prior to April 1994. At that time, information was collected retrospectively for transplants performed January 1990 - March 1994

Source: UNOS, based on OPTN data as of November 27, 2000 and *Organ Transplant Services; Regulatory Issues and Policy Options*, MHCC, released September 13, 2001

*Note: Data reported is for the nine-month period January - September 2000, the most recent data for individual program types.

Maryland has also observed a significant increase in the number of organ transplants performed. As illustrated in Table 6, the total number of Maryland transplants increased from 149 in 1990 to 731 in 1999, a fivefold increase.

Table 6
Number of Transplants By Organ Type and Hospital: Maryland, 1990 to 1999

Transplant Type	Hospital											
		1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	TOTAL
<i>Kidney</i>	Johns Hopkins Bayview Med Ctr	19	24	33	35	31	32	32	1	0	0	
	Johns Hopkins Hospital	60	45	40	53	59	66	70	113	118	164	
	Shady Grove Adventist Hospital	-	-	0	0	2	2	5	3	4	-	
	University of Maryland Medical System	12	42	76	106	114	141	165	197	257	329	
	Subtotal	91	111	149	194	206	241	272	314	379	493	2,450
<i>Liver</i>	Johns Hopkins Hospital	37	43	54	54	61	50	45	46	65	53	
	University of Maryland Medical System	-	-	-	-	1	17	29	24	15	23	
	Subtotal	37	43	54	54	62	67	74	70	80	76	617
<i>Pancreas</i>	Johns Hopkins Hospital	0	0	1	1	2	1	3	8	2	11	
	University of Maryland Medical System	-	0	5	8	16	15	43	43	39	69	
	Subtotal	0	0	6	9	18	16	46	51	41	80	267
<i>Kidney-Pancreas</i>	Johns Hopkins Hospital	0	0	1	2	4	8	16	5	10	7	
	University of Maryland Medical System	-	9	19	23	18	47	29	23	24	14	
	Subtotal	0	9	20	25	22	55	45	28	34	21	259
<i>Heart</i>	Johns Hopkins Hospital	16	18	16	19	14	24	23	15	19	23	
	University of Maryland Medical System	2	3	6	6	3	12	9	6	6	4	
	Subtotal	18	21	22	25	17	36	32	21	25	27	244
<i>Lung</i>	Johns Hopkins Hospital	-	-	0	1	3	7	9	6	16	29	
	University of Maryland Medical System	-	-	2	3	2	10	20	8	11	4	
	Subtotal	-	-	2	4	5	17	29	14	27	33	131
<i>Heart-Lung</i>	Johns Hopkins Hospital	3	0	0	0	0	0	0	0	0	1	
	University of Maryland Medical System	-	-	-	-	-	-	1	-	0	0	
	Subtotal	3	0	0	0	0	0	1	0	0	1	5
<i>Intestine</i>	Johns Hopkins Hospital	-	-	-	-	-	0	0	1	0	0	
	Subtotal	-	-	-	-	-	0	0	1	0	0	1
	Total	149	184	253	311	330	432	499	499	586	731	3,974

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS
 UNOS Scientific Registry Data as of September 5, 2000.

a. Transplant Program Type

Data collected by UNOS indicates that the majority of patients who utilize solid organ transplant services undergo kidney and liver transplantation. Living donor kidney transplant recipients accounted for 36 percent of all recipients in 1999, up from 22 percent of recipients in

1990 and 33 percent in 1997. The number of living donor liver transplants more than doubled between 1998 and 1999, from 86 to 219 transplants. This is due primarily to the dramatic increase in living donor transplants in adults. Recipients between the ages of 35-64 accounted for 52 percent of all living donor liver transplants in 1999, up from 19 percent in 1998.⁵

b. Patient Age

Additional data collected by UNOS (Tables 7 and 8) reveals that the majority of kidney and liver organ transplant recipients are between 35 and 64 years of age. In 2000, approximately 67 percent of kidney transplant recipients fell into this age group while about 74 percent of liver transplant recipients were in this age group. The 35 to 64 year age group has remained consistently high since 1988.

Table 7
Kidney Recipients by Age: United States, 1996 to September 2000

Recipient Age	Year										Total	
	1996		1997		1998		1999		2000*			
	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS
Not Reported	0	0	0	0	0	0	13	0.1	3	0.0	16	0.0
< 1	7	0.1	4	0.0	3	0.0	8	0.1	7	0.1	29	0.1
1-5	138	1.2	131	1.1	114	0.9	131	1.0	73	0.7	587	1.0
6-10	146	1.3	137	1.2	153	1.2	139	1.1	81	0.8	656	1.1
11-17	415	3.7	403	3.5	386	3.1	451	3.6	292	3.0	1,947	3.4
18-34	2,564	22.6	2,485	21.3	2,575	20.8	2,495	20.0	1,829	18.8	11,948	20.7
35-49	4,147	36.5	4,165	35.7	4,318	34.9	4,177	33.4	3,319	34.1	20,126	34.9
50-64	3,263	28.7	3,631	31.1	3,908	31.6	4,149	33.2	3,245	33.3	18,196	31.6
65+	680	6.0	720	6.2	908	7.3	930	7.4	889	9.1	4,127	7.2
Total	11,360	100.0	11,676	100.0	12,365	100.0	12,493	100.0	9,738	100.0	57,632	100.0

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS

UNOS Scientific Registry Data as of September 5, 2000.

*Note: Data reported is for the nine-month period January - September 2000, the most recent data for individual program types.

⁵ The United Network for Organ Sharing, *Annual Report*, 2000.

Table 8
Liver Recipients by Age: United States, 1996 to September 2000

Recipient Age	Year										Total	
	1996		1997		1998		1999		2000*			
	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS	# of TxS	% of TxS
Not Reported	1	0.0	2	0.0	2	0.0	7	0.1	0	0	12	0.1
< 1	145	3.6	163	3.9	172	3.8	169	3.6	118	3.2	767	3.6
1-5	188	4.6	204	4.9	183	4.1	162	3.4	158	4.3	895	4.2
6-10	73	1.8	73	1.7	107	2.4	80	1.7	63	1.7	396	1.9
11-17	113	2.8	118	2.8	122	2.7	111	2.4	88	2.4	552	2.6
18-34	282	6.9	342	8.2	308	6.8	295	6.3	218	5.9	1,445	6.8
35-49	1,507	37.0	1,539	36.8	1,595	35.4	1,714	36.5	1,294	34.9	7,649	36.2
50-64	1,485	36.5	1,473	35.3	1,693	37.6	1,846	39.3	1,495	40.3	7,992	37.8
65+	276	6.8	263	6.3	321	7.1	312	6.6	274	7.4	1,446	6.8
Total	4,070	100.0	4,177	100.0	4,503	100.0	4,696	100.0	3,708	100.0	21,154	100.0

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS

UNOS Scientific Registry Data as of September 5, 2000.

*Note: Data reported is for the nine-month period January - September 2000, the most recent data for individual program types.

c. Average Length of Stay

The length of time a patient stays in the hospital depends on many factors, including the patient's general health before surgery, the type of transplant surgery, and how well the organ is accepted. The following table shows the number of discharges, number of days, and average length of stay (ALOS) for Maryland organ transplant programs in 2000. The ALOS ranges from 12.0 days for a patient receiving a kidney to 43.4 days for a patient undergoing a heart transplant.

Table 9
Number of Discharges, Number of Days, and Average Length of Stay for Transplants: Maryland, 2000⁶

Organ	No. of Discharges	No. of Days	ALOS
Allogeneic BMT	85	2,533	29.8
Autologous BMT	186	3,738	20.1
Heart	21	912	43.4
Heart-Lung	2	67	33.5
Kidney	604	7,244	12.0
Liver	74	2,507	33.9
Lung	24	792	33.0
Pancreas	76	1,106	14.6

Source: Maryland Health Care Commission, Maryland Hospital Discharge Abstract Data Base, Calendar Year 2000.

⁶ Because many patients are critically ill, they must be hospitalized while awaiting an organ to become available. Consequently, some of the data in this table contains a significant number of days associated with hospitalization prior to transplantation.

d. Utilization by Minorities

Nationally, minorities represent approximately 30 percent of the total number of patients who receive organ transplants. As revealed in the following table, White, African American, Asian, and Other ethnic groups showed increases in solid organ transplants between 1995 and 1999, with Asians showing the most noticeable increase of 35 percent. Only a slight decrease of 1 percent was shown regarding Hispanics.

Table 10
Number of Transplants by Ethnicity: United States, 1995 and 1999

Ethnicity	1995	1999	Percent Change
White	13,288	14,873	12%
African American	3,163	3,732	18%
Hispanic	2,061	2,049	-1%
Asian	514	694	35%
Other	319	347	9%
Not Reported	7	4	-43%
TOTAL	19,352	21,699	12%

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS
UNOS Scientific Registry Data as of September 5, 2000.

As shown in Table 11, increasing proportions of African Americans in Maryland are undergoing solid organ transplants. In 1995, African Americans accessed 133 (approximately 31 percent) of organ transplants occurring in Maryland. In 2000, the number of organ transplants accessed by African Americans increased to 255 or approximately 33 percent of the total.

Table 11
Proportion of Organ Transplants by Ethnicity: United States and Maryland, 1995 and 2000

	Ethnicity	1995	2000	Change in Proportion (1995-2000)
Maryland	White	65.9%	61.9%	-6.0%
	African American	30.9%	32.7%	5.9%
	Hispanic	1.9%	2.4%	31.2%
	Asian	1.2%	1.5%	32.6%
	Other	0.2%	1.4%	507.8%
	Not Reported	0.0%	0.0%	-
	Total	100.0%	100.0%	
		(431)	(780)	
All States	White	68.6%	67.3%	-1.9%
	African American	16.4%	17.0%	3.6%
	Hispanic	10.7%	10.7%	-0.4%
	Asian	2.6%	3.2%	19.5%
	Other	1.7%	1.9%	13.8%
	Not Reported	0.0%	0.0%	-100.00
	Total	100.0%	100.0%	
		(19,345)	(22,955)	

Source: OPTN data as of September 7, 2001 (www.optn.org accessed September 17, 2001).

Published evidence of differences in access to organ transplant services across racial or ethnic groups is very limited. The few studies addressing this issue indicate that African-American patients are placed on waiting lists at a slower rate than white patients. Factors affecting access to a waiting list include patients' socioeconomic status, attitudes toward transplantation, and referral for transplant evaluation.⁷

e. Minimum Volume/Survival Rates

The minimum volume and survival rates established by Centers for Medicare and Medicaid Services (CMS)⁸ are part of the coverage criteria for Medicare reimbursement. The minimum volume requirements are shown in Table 12 below. CMS's minimum survival rate requirements apply to established rather than new programs.

Table 12
CMS Quality Standards for Criteria for Medicare Coverage

Organ	Minimum Volume	Minimum Survival Rate	Effective Date
Kidney	15	N/A	1976
Heart	12	1-year survival rate - 73% 2-year survival rate - 65%	April 6, 1987
Liver	12	1-year survival rate - 77% 2-year survival rate - 60%	April 12, 1991
Lung/Heart-Lung	10	1-year survival rate - 69% 2-year survival rate - 62%	February 2, 1995
Pancreas - A pancreas transplant must be performed on the same day or following a Medicare-covered kidney transplant.			July 1, 1999
Intestine	10	1-year survival rate - 65%	April 1, 2001

Source: Federal Register (52 FR 10935, 56 FR 15006, 60 FR 6537).

The SHP establishes minimum volume requirements to provide a baseline for approval of new programs. The minimum and threshold volume requirements are illustrated in Table 13. Threshold volumes are intended to be a guide for measuring adverse impact on existing programs when the Commission considers the development of additional transplant program capacity.

⁷ Committee on Organ Procurement and Transplantation Policy, Institute of Medicine, *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule* (Washington, D.C.: National Academy Press, 1999), 39-47.

⁸ Formerly known as the Health Care Financing Administration or HCFA

Table 13
Minimum and Threshold Volume Requirements for Maryland Transplant Programs, 2001

Transplant Program	Minimum Annual Volume Requirements	Threshold Annual Volume Requirements
Kidney	30	50
Liver	12	20
Pancreas	12	20
Heart	12	20
Lung, Heart/Lung	12	20
Hematopoietic Stem Cell:		
Autologous	10	10
Allogeneic	10	40
Intestine/Small Bowel, Islet Cells, Hepatocytes, and Others	To be determined by the Commission on a case-by-case basis, based on the best information available at the time of application.	

Source: Maryland Health Care Commission, COMAR 10.24.15-SHP: Specialized Health Care Services-Organ Transplant Services.

f. Organ Donors

Unlike other specialized services, the number of transplant cases performed is limited by the supply of donor organs in addition to other factors. In an effort to increase donation rates for transplant recipients, the federal government announced the National Organ and Tissue Donation Initiative in December 1997. As part of this initiative, the Department of Health and Human Services (DHHS) issued a regulation requiring all Medicare-participating hospitals to refer all deaths and imminent deaths to organ procurement organizations (OPOs). The regulation became effective in August 1998.⁹ Additionally, as one of its first health initiatives, the Bush administration plans a national program to boost the number of organ donors. DHHS hopes to address the problem by issuing national donor cards that identify Americans who are willing to donate their organs and tissues after they die. Currently, states and many health groups register organ donors, but there is no national system that identifies willing donors.¹⁰

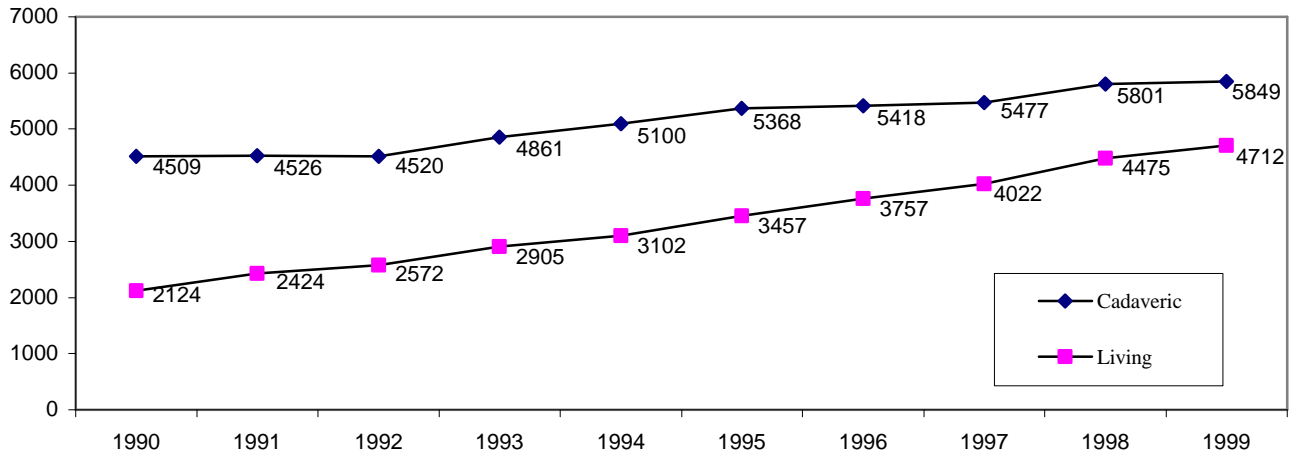
The following cadaveric and living donor characteristics were reported by UNOS in its 2000 Annual Report:

- The number of cadaveric and living donors increased by 59 percent between 1990 and 1999, from 6,633 to 10,561. The increase was especially noticeable among living donors, which more than doubled from 2,124 donors in 1990 to 4,712 in 1999. During the same period, cadaveric donors increased approximately 30 percent, from 4,509 to 5,849 (see Figure 1 below). The percentage increase in donors from 1998 to 1999 was 3 percent, compared to an 8 percent increase in donors between 1997 and 1998.

⁹ *HHS Fact Sheet*, U.S. Department of Health and Human Services, May 19, 1999, Website: www.os.dhhs.gov/news/press/1999pres/990519.html

¹⁰ "National Program Planned to Increase Organ Donors," *The Washington Post*, April 4, 2001.

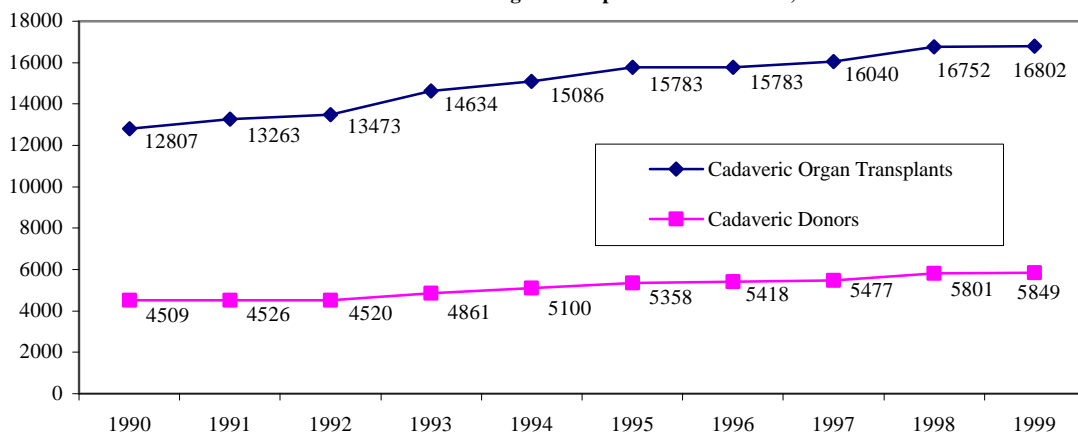
Figure 1
Cadaveric and Living Donors: United States, 1990 to 1999



Source: UNOS 2000 Annual Report

- Cadaveric donors often donate more than one organ. In 1999, an average of 3.6 organs per donor was recovered. Figure 2 shows the number of cadaveric donors and transplants over the last 10 years. Generally, the number of transplants performed each year has been nearly three times greater than the number of donors.

Figure 2
Cadaveric Donors and Cadaveric Organ Transplants: United States, 1990 to 1999

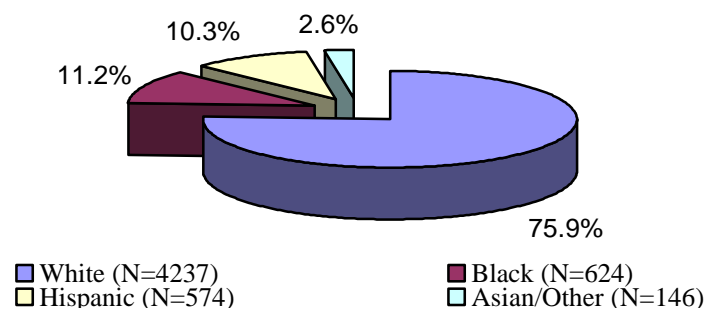


Source: UNOS 2000 Annual Report

- Living liver donors more than doubled between 1998 and 1999, from 85 to 218.

- Cadaveric pancreas donors increased 12 percent from 1998 to 1999, from 1,458 to 1,627.
- Cadaveric heart donors decreased from 2,449 in 1998 to 2,316 in 1999.
- The number of minority cadaveric donors increased from 18 percent in 1990 to 24 percent in 1999. Among minority living donors, the rate increased from 24 percent in 1990 to 28 percent in 1999. Figure 3 shows the percentage of cadaveric donors, by race and ethnicity, for 1999.

Figure 3
Cadaveric Donors by Race/Ethnicity: United States, 1999



Source: UNOS 2000 Annual Report

- Among cadaver intestine donors, 34 percent were minority donors in 1999. This reflects an increase from 16 percent in 1995 and 22 percent in 1997.
- In 1999, donors with blood type O represented 64 percent of living donors, but only 47 percent of cadaveric donors. Those with blood type A accounted for 28 percent of living donors and 38 percent of cadaveric donors.
- Among cadaveric donors in 1999, head trauma and cerebrovascular/stroke accounted for 85 percent of all causes of death.
- In 1999, nearly 95 percent of living donors were kidney donors and nearly 5 percent were liver donors.
- Among living donors, 35 percent were full siblings (including identical twins) in 1999, down from 52 percent in 1990 and 40 percent in 1997. Parent donors also decreased from 29 percent in 1990 to 21 percent in 1997, and 18 percent in 1999. Living donors increased primarily among offspring, other relatives, and unrelated donors, accounting for 45 percent of living donors in 1999. Unrelated donors quadrupled between 1990 and 1999, from 5 percent to 20 percent.

g. Ethical Issues

Despite the growing number of transplantations that occur annually, a number of ethical issues continue to prevail. The idea of transplantation is often against some people's consciences for religious or other reasons. Many feel that cadaveric organ donation is acceptable while they question the practice of transplantation between living persons.¹¹ Some disagree as to when a patient is "brain dead" and when transplantation should be considered. Others argue that transplantations from human fetuses, animal to human transplantations, and artificial substitution for tissues and organs are morally unacceptable practices.¹²

5. Cost of Organ Transplant Services

As shown on Table 14, in 2000 the average charge per discharge in Maryland ranged from \$55,249 for an autologous BMT to \$176,457 for a patient undergoing a heart transplant. Additionally, organ recipients often incur the costs of ongoing anti-rejection drugs.

Table 14
Number of Discharges and Average Charge per Discharge for
Transplants in Maryland Programs, 2000¹³

Organ	No. of Discharges	Average Charge per Discharge*
Allogeneic BMT	85	\$ 102,766
Autologous BMT	186	\$ 55,249
Heart	21	\$ 176,457
Heart-Lung	2	\$ 165,650
Kidney	604	\$ 83,133
Liver	74	\$ 166,826
Lung	24	\$ 174,523
Pancreas	76	\$ 97,942

Source: Maryland Health Care Commission, Maryland Hospital Discharge Abstract Data Base, Calendar Year 2000.

* Charges do not include additional hospital outpatient charges, prescription medications, and physicians' professional fees.

The 1972 Social Security Amendment (Public Law 92-603) instituted federally financed health care coverage for dialysis and renal transplantation, effective July 1, 1973. The cost of this program has far exceeded original expectations. Medicare spending in 1996 was estimated to be \$10.96 billion, a 12.5 percent increase from the \$9.74 billion spent in 1995. The total expenditure by all payers for treating these patients in 1996 was estimated at \$14.55 billion, up from \$13.05 billion in 1995. Although this patient population made up only 0.6 percent of the total Medicare population in 1994, it consumed 5.1 percent of Medicare

¹¹ *Organ and Tissue Transplants: Some Ethical Issues*, Paul Flaman, St. Joseph's College, University of Alberta, 1994.

¹² *Ibid.*

¹³ Because many patients are critically ill, they must be hospitalized while awaiting an organ to become available. Consequently, some of the data in this table contains charges associated with hospitalization prior to transplantation.

expenditures.¹⁴ Table 15 shows the Maryland payment source by type of organ transplant for 1999. Private health insurance companies are the primary source of reimbursement for organ transplant surgery, except for kidney and combined kidney-pancreas organ transplants. Medicare covers kidney and combined kidney-pancreas transplants at a greater rate than other transplants due to their coverage under end-stage renal failure.

Table 15
Payment Source by Type of Organ Transplant: Maryland, 1999

Payer Type	Organ type								
	All Organs	Kidney	Liver	Pancreas	Kidney-Pancreas	Heart	Lung	Heart-Lung	Intestine
Medicare	32%	41%	18%	3%	32%	19%	6%	0%	0%
Foreign Govt	0%	0%	0%	0%	0%	0%	0%	0%	0%
Not Reported	9%	1%	0%	74%	9%	0%	12%	100%	0%
Medicaid	4%	4%	8%	0%	0%	4%	9%	0%	0%
US/State									
Govt Agency	1%	0%	3%	0%	0%	4%	0%	0%	0%
Private insurance	48%	46%	68%	23%	55%	59%	61%	0%	0%
HMO/PPO	6%	7%	1%	0%	5%	15%	9%	0%	0%
Self	1%	2%	0%	0%	0%	0%	0%	0%	0%
Free Care	0%	0%	1%	0%	0%	0%	3%	0%	0%
Dept Veterans Affairs	0%	0%	0%	0%	0%	0%	0%	0%	0%

Source: OPTN data as of September 7, 2001 (www.optn.org accessed September 17 2001).

Medicare covers kidney, heart, liver, heart/lung, and lung transplants in an approved facility for eligible patients. Additionally, bone marrow transplants are covered, but only under specific diagnoses. Medicare Part B reimburses for immunosuppressive drugs for a period of time beginning with the discharge date of the transplant hospital stay.¹⁵ Effective April 1, 2001, Medicare covers intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. This transplantation is covered only when performed for patients who have failed total parenteral nutrition (TPN), and only when performed in centers that meet approval criteria.¹⁶ Effective July 1, 1999, Medicare covers pancreas transplantation "when it is performed simultaneously with or following a kidney transplant."¹⁷

Concerning allogeneic stem cell transplantation, donor expenses are a covered benefit to the recipient/beneficiary, but except for physician services, are not paid separately. Services

¹⁴ (U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000. <http://www.health.gov/healthypeople/> accessed September 19, 2001)

¹⁵ Transplant Resource Directory, *Coverage for Health Care/Medications*, WEBSITE: <http://www.stadtlander.com>, accessed April 2, 2001.

¹⁶ Maryland Medicare Part A, *Bulletin*, WEBSITE, <http://www.marylandmedicare.com>, January 4, 2001.

¹⁷ Maryland Medicare Part A., *Bulletin*, WEBSITE, <http://www.carefirst.com>, September 21, 2000.

provided to the donor include physician services, hospital care in regarding screening the stem cell, and usual follow-up care. Since there are no covered acquisition charges for autologous stem cell transplants, charges are shown in the usual manner. The transplant hospital maintains an itemized statement that identifies the services that are provided, the charges, the person receiving the service, and whether the person is a potential transplant donor or recipient. These charges are reflected in the transplant hospital's stem cell/bone marrow acquisition cost center.¹⁸

6. Future Utilization of Organ Transplant Services

There are several factors that affect the current utilization and future growth of organ transplant services both nationally and in Maryland. For example, increasing the public's willingness to consent to donation also increases the supply. Similarly, donor campaigns and public education boost the growth of organ transplant services. The Amoss Bill, passed by the Maryland General Assembly in 1998 and patterned after Pennsylvania Act 102 enacted in 1994, is designed to increase the supply of donated organs through improved hospital participation to identify more potential donors, and to provide for public education. Additionally, the Amoss Bill establishes an Organ and Tissue Donation Awareness Fund to promote public education and awareness about organ donation. A report issued by DHMH on February 8, 2001 revealed a nearly 100 percent compliance by hospitals with the Amoss statute. In addition, the report indicated that organ donations rose to 334 in 1999-2000 (the first two years under the Amoss Act). This reflects a 31 percent increase over the 254 organs that were donated during the two years immediately prior to the legislation's passage. Likewise, tissue donations increased by 61 percent to 626 during the same two-year period, up from 390 for the prior two years.¹⁹

a. New Medications/Advanced Technology

With continuing discoveries of new medications and advances in medical technology, solid organ transplantation has become an increasingly successful and common medical procedure, a literal "second chance at life." More people are benefiting from organ transplants and their survival rates are steadily improving. Additionally, access to transplantation has become more equally available to potential recipients. Since the enactment of the National Organ Transplant Act of 1984 (the Act), the number of patients receiving organs has increased annually. The Act created a national transplant system to be operated by transplant professionals, with oversight by DHHS to ensure an equitable allocation system.²⁰

An article in the *USA Today* (March 30, 2001) noted that a series of experiments with laboratory animals suggests that doctors may soon be able to heal damaged hearts by reinjecting people with the body's own repair cells. According to the heart research program director at the National Heart, Blood, and Lung Institute, testing on humans could begin within three to five years.²¹

¹⁸ Ibid.

¹⁹ "Organ, Tissue Donations Spurred by Amoss Act,." *DHMH News Release*, February 8, 2001. WEBSITE: www.dhmd.state.md.us/publ-rel/amos.htm

²⁰ WEBSITE: www.gao.gov/special.pubs/organ/chapter

²¹ "Stem Cells May Repair Heart Attack Damage", *USA TODAY*, March 30, 2001.

b. Waiting List

The single most important issue in organ transplantation is the disparity between utilization and potential demand. As Figures 1 and 2 show, the number of donors and transplants is increasing; however, the number of people on the waiting list is rising faster. The following table illustrates overall national waiting list provided by UNOS in its 2000 Annual Report. The waiting list reflected 72,110 registrants on the last day of 1999, representing a 12 percent increase from the 64,473 registrants in 1998. Overall, the waiting list more than tripled between 1990 (21,914 registrants) and 1999, and the list continues to grow. As of September 7, 2001, the UNOS national patient waiting list for organ transplant totaled 78,172.²²

Table 16
National Organ Transplant Waiting List: United States, 1990 to 1999

Year	Organ Type								Total
	Kidney	Liver	Pancreas	Kidney-Pancreas	Heart	Lung	Heart-Lung	Intestine	
1990	17,883	1,237	473	-	1,788	308	225	-	21,914
1991	19,352	1,676	600	-	2,267	670	154	-	24,719
1992	22,376	2,323	126	778	2,690	942	180	-	29,415
1993	24,973	2,997	183	923	2,834	1,240	202	42	33,394
1994	27,498	4,059	222	1,067	2,933	1,625	205	75	37,684
1995	31,149	5,701	286	1,239	3,468	1,932	208	83	44,066
1996	34,646	7,480	324	1,464	3,700	2,318	237	83	50,252
1997	38,270	9,647	361	1,593	3,899	2,672	236	94	56,772
1998	42,392	12,070	456	1,842	4,185	3,171	257	100	64,473
1999	46,489	14,710	725	2,225	4,121	3,491	232	116	72,110

Source: UNOS OPTN Waiting List on the last day of each year., *Annual Report*, 2000

Table 17 shows the projected transplant cases and need for new programs by regional service area in Maryland for 2003:

²² UNOS, *Critical Data*, September 7, 2001 NOTE: UNOS/OPTN policies allow patients to be listed with more than one transplant center (multiple-listing), thus the number of registrations is greater than the actual number of patients. Some patients are waiting for more than one organ; therefore, the total number of patients is less than the sum of patients waiting for each organ.

Table 17
Projected Transplant Cases and Need for New Programs by Regional Service Area: Maryland, Target Year 2003

Type of Transplant Program/Regional Service Area	Number of Tx Programs	Ave. Annual Tx Cases (1998-2000)*	Tx Cases (2000)†	Projected Transplant Cases (2003)‡	Additional Cases (iii)	Minimum/Threshold Volume Standard	Projected > Threshold Volume (i)	Minimum Volume Standard Met (1999)	Threshold Volume Standard Met (ii)	New Program Considered
Kidney	2	502	596	731	135	30/50	Yes	2 Yes	2 Yes	Yes
Pancreas	2	81	76	90	14	12/20	No	2yes	1 No, 1Yes	No
Liver	2	79	80	82	2	12/20	No	2 Yes	2 Yes	No
Heart	2	24	21	20	-1	12/20	No	1 No, 1 Yes	1 No, 1 Yes	No
Lung	2	28	25	33	8	12/20	No	1 No, 1 Yes	1 No, 1 Yes	No
Autologous BMT	4	228	225	258	33	10/10	Yes	2 No, 2 Yes	2 No, 2 Yes	No
Allogeneic BMT	2	99	113	200	87	10/40	Yes	2 Yes	1 No, 1 Yes	No

Notes: An application for a new program will be considered only if the following criteria are met:

- i. The difference between the projected transplant cases (three-year planning horizon) and the transplant cases in the current year is greater than the threshold utilization standard;
- ii. All programs of a specific type within their region meet or exceed the threshold volume in the most current full year of data available;
- iii. There is a positive trend in the utilization of that program type in the region as a whole, over the most recent 3 years of data available; and
- iv. The introduction of a new program will not result in a center dropping below the minimum volume standards.

* Average annual transplant cases based on 1997 to 1999 data for autologous and allogeneic bone marrow transplants.

† Transplant cases based on 1999 data for autologous and allogeneic bone marrow transplants.

‡ Projected cases based on: III.B.1-Option; III.B.2-Option 1; III.B.3-Option 2 (all ages).

Source: *Organ Transplant Services: Regulatory Issues and Policy Options*, MHCC, released September 13, 2001.

C. Neonatal Intensive Care Services

1. Definition

Another component of Specialized Health Care Services under the State Health Plan addresses Neonatal Intensive Care Services (NICU). Using the Maryland Perinatal System Standards provided in the State Health Plan at COMAR 10.24.18, these NICU services are defined as Levels III, III+ and IV and are described below:

- | | |
|------------|--|
| Level III | A hospital with a perinatal program that may provide medical intensive care to newborns = 26weeks gestational age or = 800 grams, as defined by these standards. |
| Level III+ | A hospital with a perinatal program that must be geographically near a Level IV perinatal center, may provide medical intensive care for newborns of all gestational ages and birth weights, and may provide selected specialty services, as defined by these standards. |
| IV | A hospital with a perinatal program that provides comprehensive neonatal and obstetrical services including all subspecialty services, as defined by these standards. |

2. Supply and Distribution of NICU Services

In Maryland, all hospitals with perinatal services are expected to have written standards, protocols, or guidelines concerning the provision of uncomplicated and complicated obstetrical and neonatal care, including those for the following: (1) unexpected obstetrical care problems; (2) fetal monitoring; (3) performing a cesarean delivery within 30 minutes of the decision to deliver; and (4) resuscitation and stabilization of unexpected neonatal problems. Table 18 shows the acute care hospitals in Maryland that have obstetric units, including those with Level III or above NICUs.

Table 18
Obstetric Services Inventory, System Affiliation, Charge Per Case and Discharges: Maryland, 1999

Jurisdiction/ Local Health Planning Area	Hospital	Number of Beds	System Affiliation	Avg Charge per Case, CY 1999	NICU (Level III or above)	Obstetrics Discharges CY 1999
<u>Allegany</u>	Memorial of Cumberland Hosp	9	Western Md Hlth System	\$3,870		479
	Sacred Heart Hospital	10	Western Md Hlth System	\$2,825		635
<u>Carroll</u>	Carroll Co. General Hospital	12		\$3,391		1,282
<u>Frederick</u>	Frederick Memorial Hospital	21		\$2,661		1,962
<u>Garrett</u>	Garrett Co. Memorial Hospital	7		\$3,077		336
<u>Washington</u>	Washington County Hospital	22		\$2,510		1,821
WESTERN MARYLAND TOTAL		81		\$3,056		6,515
<u>Montgomery</u>	Holy Cross Hospital	71		\$3,245	yes	7,301
	Montgomery General Hospital	18		\$3,611		915
	Shady Grove Adventist Hospital	54	Adventist Hlth Care	\$3,340	yes	5,202
	Washington Adventist Hospital	31	Adventist Hlth Care	\$3,954		2,457
MONTGOMERY COUNTY TOTAL		174		\$3,538		15,875
<u>Calvert</u>	Calvert Memorial Hospital	8		\$3,041		819
<u>Charles</u>	Civista Medical Center	15		\$3,100		1,027
<u>Prince George's</u>	Laurel Regional Hospital	21	Dimensions Hlth System	\$4,324		993
	Prince George's Hospital Cntr	42	Dimensions Hlth System	\$3,517	yes	3,137
	Southern Maryland Hosp Cntr	30		\$4,165		1,856
<u>St. Mary's</u>	St. Mary's Hospital	13		\$3,369		899
SOUTHERN MARYLAND TOTAL		129		\$3,586		8,731
<u>Anne Arundel</u>	Anne Arundel Medical Center	46		\$3,647	yes	4,252
<u>Baltimore Cnty</u>	Franklin Square Hospital	57	MedStar Health	\$3,981	yes	3,037
	Greater Baltimore Medical Cntr	54		\$3,725	yes	5,068
	St. Joseph Hospital	38		\$3,166	yes	2,507
	Harbor Hospital	38	MedStar Health	\$3,778	yes	1,928
<u>Baltimore City</u>	Johns Hopkins Bayview M.C.	16	Johns Hopkins Hlth System	\$4,776	yes	1,379
	Johns Hopkins Hospital	40	Johns Hopkins Hlth System	\$4,561	yes	2,236
	Maryland General Hospital	20	Univ of Md Med System	\$5,889		977
	Mercy Medical Center	34		\$4,144	yes	3,371
	Sinai Hospital of Baltimore	31	Life Bridge Health	\$4,542	yes	2,359
	St. Agnes Hospital	34		\$4,661	yes	2,269
	Union Memorial Hospital	20	MedStar Health	\$4,144	yes	906
	University of Maryland	32	Univ of Md Med System	\$5,359	yes	1,621
	Harford Memorial Hospital	30	Upper Chesapeake Hlth Sys	\$2,762		726
	Howard Co. General Hospital	32	Johns Hopkins Hlth System	\$3,252	yes	3,103
CENTRAL MARYLAND TOTAL		522		\$4,159		35,739
<u>Cecil</u>	Union Hospital of Cecil	11		\$3,310		798
<u>Kent</u>	Kent & Queen Anne's Hospital	4		\$3,149		252
<u>Talbot</u>	Memorial Hospital at Easton	25	Shore Health System	\$3,543		1,097
<u>Wicomico</u>	Peninsula Regional Med Cntr	31		\$3,225		2,290
EASTERN SHORE TOTAL		71		\$3,307		4,437
MARYLAND TOTAL*		977		\$3,529		71,297

Source: Maryland Health Care Commission (Obstetric discharges and average charge per case are from the Hospital Discharge Abstract Database for 1999, and the bed inventory is from the Office of Health Care Quality)

* Total discharges and average charge per case include data only for hospitals with an obstetric service. The detailed tables in the appendix include data from hospitals without an obstetric service.

The number and distribution of all births, infants with low birth weights, infants with very low birth weights, and neonatal deaths in Maryland in 1999 is identified in Table 19. Approximately 33 percent of Maryland births occurred in Montgomery and Prince George's Counties, 12,369 and 11,900 respectively. These counties, along with Baltimore City, showed the most number of low birth weights, very low birth weights, and neonatal deaths. On a statewide level, 7,961 (approximately 11 percent) of the births were classified as either low birth weights or very low birth weights.

Table 19
Number of All Births, Infants with Low Birth Weights, Infants with Very Low Birth Weights, and Neonatal Deaths by Jurisdiction: Maryland, 1999

Jurisdiction/Local Health Planning Region	All Births	Infants with Low Birth Weights*	Infants with Very Low Birth Weights**	Neonatal Deaths
Allegany County	728	48	5	2
Carroll County	1,828	100	16	3
Frederick County	2,595	186	37	12
Garrett County	355	24	5	2
Washington County	1,646	111	13	4
Western Maryland Total	7,152	469	76	23
Montgomery County	12,369	977	204	55
Montgomery County Total	12,369	977	204	55
Calvert County	956	51	7	5
Charles County	1,675	140	26	7
Prince George's County	11,900	1,176	311	90
St. Mary's County	1,303	80	14	5
Southern Maryland Total	15,834	1,447	358	107
Anne Arundel County	6,660	486	100	32
Baltimore County	9,003	800	180	50
Baltimore City	9,734	1,456	361	89
Harford County	2,925	213	39	20
Howard County	3,372	221	40	12
Central Maryland Total	31,694	3,176	720	203
Caroline County	363	28	6	7
Cecil County	1,168	108	22	8
Dorchester County	314	29	3	0
Kent County	211	20	2	1
Queen Anne's County	477	35	8	3
Somerset County	253	34	10	1
Talbot County	332	26	2	0
Wicomico County	1,126	120	27	7
Worcester County	529	46	8	2
Eastern Shore Total	4,773	446	88	29
Maryland Total	71,822	6,515	1,446	417

Source: Maryland Vital Statistics, *Annual Report 1999*

* Low Birth Weight = <2,500 grams

** Very Low Birth Weight = <1,500 grams

NOTE: A hospital with a Level II perinatal program may provide care to newborns ≥ 32 weeks gestational age or $\geq 1,500$ grams.

3. Trends in the Utilization of NICU Services

a. Risk Factors and Mortality

In Maryland in 2000, the average length of stay for neonatal discharges was 6.6 days. As shown in Table 20, a baby diagnosed with extreme immaturity or respiratory distress syndrome spent approximately 50 days in a hospital. The average length of stay for babies classed as normal newborns was 4.2 days.

Table 20
Neonatal Discharges and Average Length of Stay (in Days) by Diagnosis Related Group: Maryland, 2000

DRG	DRG Description	Discharges	ALOS
385	Neonates, Died or Transferred to Another Acute Care Facility	974	17.2
386	Extreme Immaturity or Respiratory Distress Syndrome of Neonate	1,448	49.9
387	Prematurity with Major Problems	1,969	23.5
388	Prematurity without Major Problems	2,670	8.0
389	Full Term Neonate with Major Problems	7,090	7.6
390	Neonate with Other Significant Problems	12,769	4.8
391	Normal Newborn	40,936	4.2
	Total	67,856	6.6

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), June 2001.

As shown in Table 21, the percent of discharges coded as low birth weight was higher for babies born in a hospital without a NICU when compared to babies born in a hospital with a NICU, 82.0 percent and 78.2 percent respectively. Likewise, when babies were admitted from home to a hospital without a NICU, the percent of discharges coded as low birth weight was 14.0 percent, while the percent of discharges admitted to a hospital with a NICU was 11.4.

Table 21
Number and Percent of Discharges Coded as Low Birth Weight (<2,500 Grams) by Source of Admission and Category of Hospital: Maryland, 2000

Source of Admission	Category of Hospital			
	Without NICU		With NICU	
	LBW Discharges		LBW Discharges	
	No.	%	No.	%
Home	217	14.0	514	11.4
Born in Hospital	1,272	82.0	3,515	78.2
Acute Hospital to MIEMSS-Designated Center	0	0.0	33	0.7
Acute Hospital for Other Reason	38	2.5	69	1.5
Other	24	1.5	364	8.1
Total	1,551	100.0	4,495	99.9

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), June 2001.

Notes: During the reporting period, all hospitals with NICUs were designated by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) as perinatal referral centers.

Home includes Physician's Office of any Noninstitutional source. Other includes On-Site Subacute Unit, Other Subacute Facility, Off-Site Ambulatory/Outpatient Surgery Unit or Other Outpatient Setting at Another Hospital, or Health Care Facility (admission within 72 hours), On-Site Ambulatory/Outpatient Surgery Unit or Room in which Ambulatory Surgery is performed (admission within 72 hours), Nursing Home, Any Other Health Institution, and Unknown.

Percents may not total 100.0 due to rounding.

Table 22 reveals for both hospitals without NICUs and hospitals with NICUs, the majority of discharges coded as low birth weight babies were sent home after delivery, 77.2 percent and 80.4 percent respectively.

Table 22
Number and Percent of Discharges Coded as Low Birth Weight (<2,500 Grams) by Disposition of Patient and Category of Hospital: Maryland, 2000

Disposition of Patient's Stay	Category of Hospital			
	Without NICU		With NICU	
	LBW Discharges		LBW Discharges	
	No.	%	No.	%
Acute Care General Hospital	157	10.1	159	3.5
Died	38	2.5	187	4.2
Home Health Care	127	8.2	340	7.6
Home	1,198	77.2	3,613	80.4
Other	31	2.0	196	4.4
Total	1,551	100.0	4,495	100.1

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), June 2001.

Notes: Other includes Discharge to Nursing Facility, Discharge to On-Site Subacute Unit, Discharge to Other Subacute Facility, Do Not Use, Left Against Medical Advice, Discharge to Rehabilitation Facility, Discharge to On-Site Distinct Rehabilitation Unit, and Discharge to Other Health Care Facility.

Percents may not total 100.0 due to rounding.

As shown in Table 23, Medicaid was the highest expected payer of medical expenses for low birth weight babies in hospitals without NICUs (48.9 percent) as well as hospitals with NICUs (42.2 percent). Self-payers consisted of 1.7 percent of discharges from hospitals without NICUs and 1.4 percent of discharges from hospitals with NICUs.

Table 23
Number and Percent of Discharges Coded as Low Birth Weight (<2,500 Grams) by Payer and Category of Hospital: Maryland, 2000

Expected Payer for Most of Bill	Category of Hospital			
	Without NICU		With NICU	
	LBW Discharges		LBW Discharges	
	No.	%	No.	%
Blue Cross	156	10.1	621	13.8
Commercial	187	12.1	486	10.8
HMO	394	25.4	1,360	30.3
Medicaid	759	48.9	1,895	42.2
Self-Pay	28	1.8	70	1.6
Other	27	1.7	63	1.4
Total	1,551	100.0	4,495	100.1

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), June 2001.

Notes: Blue Cross includes Blue Cross of Maryland, Blue Cross of the National Capital Area, and Blue Cross (Other States). Commercial includes Commercial Insurance/PPO. HMO includes Managed Care payers other than Medicare and Medicaid. Medicaid includes Medicaid, and Medicaid Managed Care. Other includes Medicare, Medicare Managed Care, Other Government Program, Unknown, Workers' Compensation, and Other.
Percents may not total 100.0 due to rounding.

One of the goals of perinatal regionalization is the delivery and care of newborns in risk-appropriate facilities. CON review is one mechanism to avoid the unnecessary duplication of facilities in a region while achieving this goal. CON regulations, or the State Health Plan that includes the methodologies, standards, and criteria for CON review, may be written to set forth specific requirement for providing access to services, promoting quality of care, and containing costs.

The data in the following tables shows that hospitals without neonatal intensive care units reported about 200 discharges of newborns of very low birth weight (VLBW = < 1,500 grams) in calendar year 2000. Further, the data indicate relatively low utilization rates of existing NICUs. The Maryland Perinatal Health Initiative has identified goals to reduce the number of VLBW births in Level I and II hospitals, and the VLBW-specific neonatal mortality rates in Level III, III+, and IV hospitals. The potential exists, particularly in metropolitan areas where specialists represent a larger percentage of physicians, for hospitals to upgrade their perinatal services and increase the supply of NICUs without improving distribution or access significantly. The growth in supply can, however, increase the costs for equipment and staffing associated with the NICU.

Table 24
Number, Percent, and Average Length of Stay (ALOS in Days) of Discharges Coded as Very Low Birth Weight (<1,500 Grams) by Source of Admission and Category of Hospital: Maryland, 2000

Source of Admission	Category of Hospital					
	Without NICU VLBW Discharges			With NICU VLBW Discharges		
	No.	%	ALOS	No.	%	ALOS
Home	40	20.0	2.8	135	11.9	27.5
Born in Hospital	134	67.0	8.5	886	78.0	42.4
Acute Hospital to MIEMSS-Designated Center	0	0.0	0.0	11	1.0	41.5
Acute Hospital for Other Reason	16	8.0	15.1	28	2.5	45.8
Other	10	5.0	15.3	76	6.7	47.9
Total	200	100.0	8.2	1,136	100.1	41.1

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), August 2001.

Notes: During the reporting period, all hospitals with NICUs were designated by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) as perinatal referral centers.
Home includes Physician's Office or any Noninstitutional source. Other includes On-Site Subacute Unit, Other Subacute Facility, On-Site Ambulatory/Outpatient Surgery Unit or Room in which Ambulatory Surgery is performed (admission within 72 hours), Nursing Home, Any Other Health Institution, and Unknown.
Percents may not total 100.0 due to rounding.
Newborn birth weight, source of admission, and discharge disposition may not have been coded as defined in COMAR 10.37.06 Submission of Hospital Discharge Data Set to the Health Services Cost Review Commission.

Table 25
Number, Percent, and Average Length of Stay (ALOS in Days) of Discharges Coded as Very Low Birth Weight (<1,500 Grams) by Disposition of Patient and Category of Hospital: Maryland, 2000

Source of Admission	Category of Hospital					
	Without NICU VLBW Discharges			With NICU VLBW Discharges		
	No.	%	ALOS	No.	%	ALOS
Acute Care General Hospital	56	28.0	1.5	103	9.1	44.1
Died	36	18.0	0.1	158	13.9	7.0
Home Health Care	9	4.5	42.4	92	8.1	63.1
Home	87	43.5	12.7	672	59.2	44.9
Other	12	6.0	5.8	111	9.8	45.4
Total	200	100.0	8.2	1,136	100.1	41.1

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), August 2001.

Notes: Other includes Discharge to Nursing Facility, Discharge to On-Site Subacute Unit, Discharge to Other Subacute Facility, Do Not Use, Left Against Medical Advice, Discharge to Rehabilitation Facility, Discharge to On-Site District Rehabilitation Unit, and Discharge to Other Health Care Facility.
Percents may not total 100.0 due to rounding.
Newborn birth weight, source of admission, and discharge disposition may not have been coded as defined in COMAR 10.37.06 Submission of Hospital Discharge Data Set to the Health Services Cost Review Commission.

Table 26
Number, Percent, and Average Length of Stay (ALOS in Days) of Discharges Coded as Very Low Birth Weight (<1,500 Grams) by Payer and Category of Hospital: Maryland, 2000

Expected Payer for Most of Bill	Category of Hospital					
	Without NICU VLBW Discharges			With NICU VLBW Discharges		
	No.	%	ALOS	No.	%	ALOS
Blue Cross	17	8.5	8.8	171	15.1	35.2
Commercial	25	12.5	11.0	118	10.4	43.7
HMO	43	21.5	10.3	336	29.6	40.9
Medicaid	86	43.0	8.2	467	41.1	44.7
Self-Pay	10	5.0	4.1	20	1.8	18.4
Other	19	9.5	1.7	24	2.1	22.0
Total	200	100.0	8.2	1,136	100.1	41.1

Source: Maryland Health Care Commission (based on discharge abstract data reported by Maryland hospitals to the Health Services Cost Review Commission), June 2001.

Notes: Blue Cross includes Blue Cross of Maryland, Blue Cross of the National Capital Area, and Blue Cross (Other State). Commercial includes Commercial Insurance/PPO. HMO includes Managed Care Payers other than Medicare and Medicaid. Medicaid includes Medicaid and Medicaid Managed Care. Other includes Medicare, Medicare Managed Care, Other Government Program, Unknown, Workers' Compensation, and Other.

Percents may not total 100.0 due to rounding.

Lifestyle behaviors during pregnancy such as cigarette smoking, drug and/or alcohol use, nutrition and excessive weight gain are significant preventable risk factors that affect low birth weight and prematurity. Cigarette smoking is the largest known risk factor concerning low birth weight. Approximately 20 percent of all low birth weight could be avoided if women did not smoke during pregnancy.²³ As shown in Table 27, smokers in all age categories had a higher risk of delivering low birth weight babies when compared to nonsmokers.

²³ The Role of Lifestyle in Preventing Low Birth Weight: Spring 1995. Website: <http://www.futureofchildren.org/LBW/09LBWCHO.htm>

Table 27
Percent Low Birth Weight by Smoking Status, Age, and Race of Mother: United States, 1997

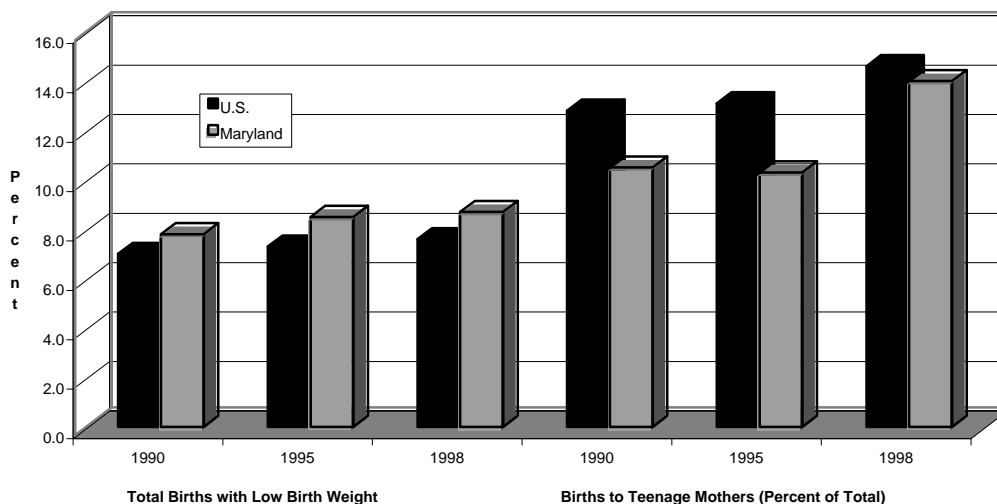
Smoking Status & Race of Mother	Age of Mother								
	All Ages	<15	Total	15-17	18-19	20-24	25-29	30-34	35-39
All Races	7.8	14.2	9.9	10.7	9.4	7.7	6.8	7.1	8.6
Smoker	12.1	15.7	11.4	12.1	11.1	10.4	11.4	13.6	16.8
Nonsmoker	7.1	13.9	9.5	10.5	9.0	7.1	6.2	6.4	7.5
White	6.6	12.1	8.4	9.1	8.1	6.5	5.9	6.2	7.4
Smoker	10.7	17.2	10.9	11.5	10.6	9.7	10.0	11.4	14.2
Nonsmoker	5.9	10.9	7.7	8.4	7.3	5.7	5.2	5.5	6.6
African American	13.1	16.3	13.4	14.0	12.9	12.0	12.4	13.8	16.2
Smoker	21.3	(B)	16.4	16.9	16.1	16.2	21.7	26.1	28.8
Nonsmoker	12.2	16.3	13.1	13.8	12.6	11.5	11.3	11.9	13.7

Source: U.S. Census Bureau, Statistical Abstract of the United States: 2000

NOTES: "All Races" includes races other than White and African American. (B) Base data too small to meet statistical standards of reliability. Excludes California, Indiana, New York, and South Dakota, which did not require reporting of tobacco use during pregnancy.

Reducing the use of alcohol and other drugs during pregnancy could also reduce the rate of low birth weight births. Additionally, babies born to adolescents (younger than 18 years of age), who are more likely to seek prenatal care later in their pregnancies, are at greater risk for low birth weight, prematurity, and infant mortality. As shown in Figure, Maryland's percent of mothers giving birth to infants with low birth weight exceeds the nationwide percentages during the 1990 to 1998 period. However, the number of births to teenage mothers in Maryland was less than the nationwide percentages during the eight-year period.

Figure 4
Low Birth Weight and Births to Teenage Mothers, Maryland vs. U.S: 1990 to 1998



Source: U.S. National Center for Health Statistics, *Vital Statistics of the United States*, Annual; and *National Vital Statistics Reports (NVSR)* (formerly *Monthly Vital Statistics Report*).

Note: Represents registered births. Excludes births to nonresidents of the United States. Based on 100 percent of births in all states and the District of Columbia.)

Preliminary data released from the Center for Disease Control and Prevention reveals that the overall birth rate for females aged 15 to 17 in the United States in 1999 was 28.7. In 2000, the figure decreased 4 percent to 27.5.²⁴ Similarly, a report released by Maryland Vital Statistics shows that the overall birth rate for females under the age of 18 in Maryland decreased approximately 8 percent from 1999 to 2000, 3.9 and 3.6 respectively.²⁵

Low birth weights and infant mortality rates are also higher for infants whose mothers are older than 40 years of age, and it appears that a growing number of women across the United States are having their first baby at age 40 or older. As reported by the Center for Disease Control and Prevention, the birth rate for women between 40 and 44 years increased between 1999 and 2000, from 7.4 to 7.9 per 1,000 births. Likewise, the birth rate for women aged 45-54 years increased from 0.4 to 0.5.²⁶

b. Utilization by Minorities

Historically, Maryland's overall infant mortality rate has been higher than the national rate. In 1999, the most recent year for which national infant mortality rates have been published, the national infant mortality rate was 7.1 per 1,000 live births. Even though this rate is lower than the most recent rate in Maryland (7.4 in 2000, see Table 28), both African American and

²⁴ Center for Disease Control and Prevention, National Vital Statistics Reports, *Births: Preliminary Data for 2000*, Volume 49, Number 5, July 24, 2001.

²⁵ Maryland Department of Health and Mental Hygiene, Maryland Vital Statistics, *2000 Preliminary Report*

²⁶ Center for Disease Control and Prevention, National Vital Statistics Reports, *Births: Preliminary Data for 2000*, Volume 49, Number 5, July 24, 2001.

white infant mortality rates in Maryland in 2000 were lower than the most recently available national rates. For example, the rate for African American infants was 13.1 in 2000 compared with a U. S. rate of 14.6 in 1999. And, among white infants, the rate was 4.7 in 2000 compared with a national rate of 5.8 in 1999.²⁷ According to the Maryland Vital Statistics Administration, the reason that the infant mortality rate is higher in Maryland when compared to the U.S., despite the fact that race-specific rates are not, is because the proportion of births to African Americans is twice as high in Maryland as in the U.S., and African Americans have a much higher infant mortality rates than whites.²⁸

In an article published in *Future of Children*, "African American mothers are more likely to have less education, not to be married, and to be younger than white mothers."²⁹ African American women also have higher rates of hypertension, anemia, and low-level lead exposure than other groups of women. These medical conditions are likely to increase the risk of having low birth weight babies.

According to an annual report recently published by the Maryland Department of Health and Mental Hygiene (DHMH), Maryland's infant mortality rate fell to a record low of 7.4 deaths per 1,000 live births in 2000.³⁰ This figure is 10.7 percent lower than the previous low of 8.3 set in 1999. (See Figure 5 and Table 26) Mortality rates decreased among both white and African American infants between 1999 and 2000, 7.7 and 10.3 percent respectively. Despite these advances, the 2000 infant mortality rate for African American infants was 2.8 times higher than the rate for white infants. This ratio was identical to the ratio for the preceding two years.³¹

²⁷ Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*.

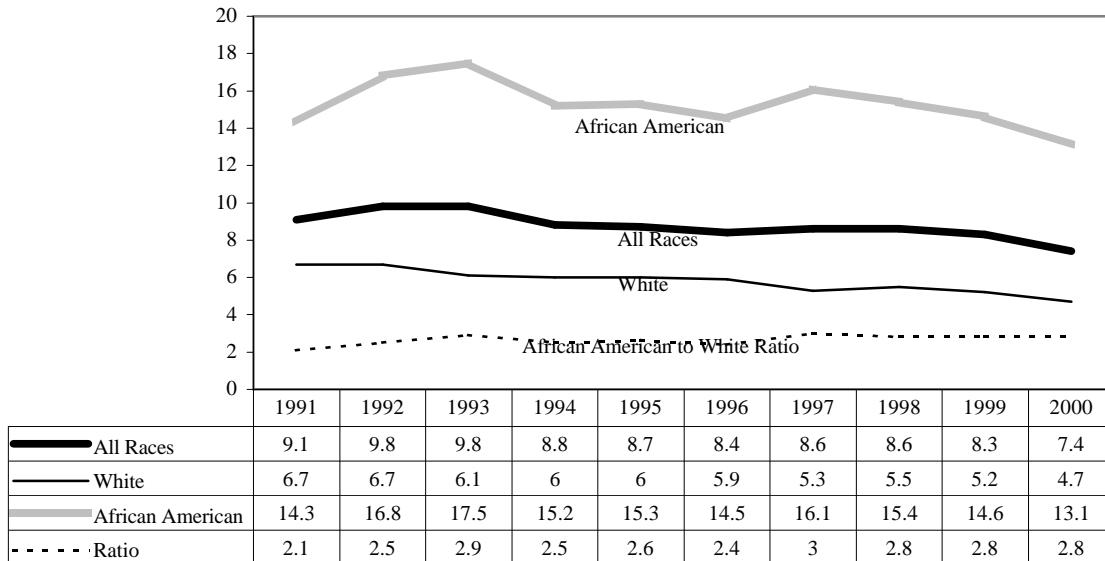
²⁸ Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*.

²⁹ The Role of Lifestyle in Preventing Low Birth Weight: Spring 1995. Website:
<http://www.futureofchildren.org/LBW/09LBWCHO.htm>

³⁰ Comparable figures for 2000 for the United States were unavailable at the time of the writing of this Working Paper.

³¹ Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

Figure 5
Infant Mortality Rates by Race and African American to White Ratio:
Maryland, 1991-2000



Source: Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

Table 28
Infant, Neonatal, and Postneonatal Mortality Rates and Percent Change in Rates: Maryland, 1999 to 2000

			Rate		
	Number of Deaths		1999	2000	Percent Change* 1999-2000
	1999	2000			
Infant Mortality**					
All Races***	596	550	8.3	7.4	-10.7
White	223	211	5.1	4.7	-7.7
African American	349	322	14.7	13.1	-10.3
Neonatal Mortality**					
All Races***	417	407	5.8	5.5	-5.6
White	150	156	3.4	3.5	1.5
African American	249	240	10.5	9.8	-6.3
Postneonatal Mortality**					
All Races***	179	143	2.5	1.9	-22.7****
White	73	55	1.7	1.2	-26.5
African American	100	82	4.2	3.3	-20.3

Source: Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

* Percent change is based on the exact rates and not the rounded rates presented here

** Per 1,000 live births

*** Includes races other than White and African American

**** Rates for 1999 and 2000 differ significantly ($p < .05$)

A more specific breakdown of infant deaths and infant mortality rates by race and jurisdiction/health planning region in Maryland for 1999 and 2000 is provided in Table 29. As

reflected in the table, infant mortality rates in 2000 ranged from a low of 2.8 per 1,000 live births in Frederick County to a high of 22.1 per 1,000 live births in Caroline County. The highest race-specific rates in Maryland for the second consecutive year were seen in Caroline County, 9.0 regarding the white infant mortality rate and 73.5 relating to the African American rate. The overall and African American infant mortality rates exhibited the most significant declines between 1999 and 2000. The overall rate fell by 37.2 percent, from 7.0 to 4.4 while the African American rate declined by 43.9 percent, from 17.4 to 9.7. Conversely, the African American infant mortality rate in Howard County rose dramatically between 1999 and 2000, from a rate of 6.0 to a rate of 21.4.³²

³² Department of Health and Mental Hygiene, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

Table 29: Infant Deaths and Infant Mortality by Race and Jurisdiction/Local Health Planning Region: Maryland, 1999 and 2000

	All Races					White					African American				
Jurisdiction/Local Health Planning Region	Number of Infant Deaths		Infant Mortality Rates *		Percent Change	Number of Infant Deaths		Infant Mortality Rates *		Percent Change	Number of Infant Deaths		Infant Mortality Rates *		Percent Change
Year	1999	2000	1999	2000	1999-2000	1999	2000	1999	2000	1999-2000	1999	2000	1999	2000	1999-2000
Allegany County	4	4	5.5	5	-8.3	4	4	5.7	5.2	-8.2	0	0	0	0	-
Carroll County	7	7	3.8	3.7	-3.6	6	7	3.4	3.8	12.3	1	0	29.4	0	-100
Frederick County	15	8	5.8	2.8	-52.4	10	6	4.3	2.3	-46.1	3	2	17.9	9.6	-46.2
Garrett County	3	2	8.5	6	-28.9	3	2	8.5	6	-28.9	0	0	-	-	-
Washington County	6	9	3.6	5.6	54.2	6	7	3.9	4.7	20.3	0	2	0	18.2	-
Western Maryland Total	35	30				29	26				4	4			
Montgomery County	86	57	7	4.4	-37.2***	33	27	4	3.3	-18.9	41	25	17.4	9.7	-43.9***
Montgomery County Total	86	57				33	27				41	25			
Calvert County	6	5	6.3	4.9	-22.3	3	5	3.6	5.7	57.9	3	0	27	0	-100.0
Charles County	11	16	6.6	9.2	39.5	8	8	7.2	7.1	-1.1	3	8	6	14.8	147
Prince George's County	123	121	10.3	9.7	-5.8	20	21	6.2	6.4	2.4	102	98	12.9	11.9	-7.9
St. Mary's County	7	12	5.4	9.9	83.8	4	6	3.7	5.9	61.5	3	6	17.3	33.5	93.3
Southern Maryland Total	147	154				35	40				111	112			
Anne Arundel County	47	43	7.1	6.3	-10.3	30	27	5.6	4.9	-12.2	16	13	15.5	12.8	-17.6
Baltimore County	68	60	7.6	6.4	-15.5	31	25	5.1	4	-21.7	34	34	13.7	13	-5.2
Baltimore City	131	113	13.5	11.7	-12.9	19	16	8.2	6.7	-18	111	95	15.6	13.5	-13.2
Harford County	22	16	7.5	5.4	-28	11	12	4.4	4.7	8.4	11	4	33.5	11.8	-64.9
Howard County	18	27	5.3	7.6	42	13	14	5.2	5.3	3.1	3	11	6	21.4	258.1***
Central Maryland Total	286	259				104	94				175	157			
Caroline County	8	9	22	22.1	0.3	4	3	13.8	9	-34.7	3	5	46.9	73.5	56.9
Cecil County	13	10	11.1	8.8	-21	11	8	10	7.4	-25.9	2	2	39.2	44.4	13.3
Dorchester County	2	3	6.4	9.1	43.6	1	1	5.3	5	-5.5	1	2	8.7	17.1	96.6
Kent County	1	1	4.7	4.9	3.9	1	1	6.3	6.1	-3	0	0	0	0	-
Queen Anne's County	3	2	6.3	4	-36.4	1	1	2.3	2.2	-4.4	1	1	24.4	27	10.8
Somerset County	1	2	4	7.3	85.3	0	1	0	6.3	-	1	1	9.4	9	-4.5
Talbot County	0	3	0	8.1	-	0	1	0	3.5	-	0	2	0	28.2	-
Wicomico County	12	16	10.7	13.6	27.9	3	6	4.3	8.4	96.1	9	9	22.6	22.1	-2.2
Worcester County	2	4	3.8	8.1	113.3	1	2	2.7	5.3	98.4	1	2	7.5	18.3	144
Eastern Shore Total	42	50				22	24				18	24			
Maryland Total	596	550	8.3	7.4	-10.7	223	211	5.1	4.7	-7.7	349	322	14.7	13.1	-10.3

Source: DHMH, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

*Per 1,000 live births by race of mother, **Percent change is based on the exact rates and not on the rounded rates presented here, *** Rates for 1999 and 2000 differ significantly (p<.05)

While low birth weight and infant mortality are closely related to socioeconomic disadvantage, socioeconomic status is difficult to measure accurately. "Educational attainment, marital status, maternal age, and income are interrelated factors and are often used to approximately socioeconomic status, but no single factor truly measures its underlying influence."³³ Low educational attainment is often associated with higher rates of low birth weight. "Marital status may also serve as a marker for the 'wantedness' of the child, the economic status of the mother, and the social support that the mother has--all of which are factors that may influence the health of the mother and infant."³⁴

c. Cause of Death

Nationally, as shown in Table 30, infant deaths and infant mortality rates have decreased from 38,351 in 1990 to 28,488 in 1998. Disorders relating to short gestation and unspecified low birth weight have remained steady during the eight-year period, with only a slight decrease in 1995.

Table 30
Infant Deaths and Infant Morality Rates by Cause of Death: United States, Selected Years, 1990 to 1998

Cause of Death	Number			Percent Distribution			Infant Mortality Rate*		
	1990	1995	1998	1990	1995	1998	1990	1995	1998
Total	38,351	29,583	28,488	100	100	100	9.2	7.6	7.2
Congenital anomalies	8,239	6,554	6,266	21	22	22	2.0	1.7	1.6
Disorders relating to short gestation and unspecified low birth weight	4,013	3,933	4,011	10	13	14	1.0	1.0	1.0
Sudden infant death syndrome	5,417	3,397	2,529	14	11	9	1.3	0.9	0.6
Respiratory distress syndrome	2,850	1,454	1,328	7	5	5	0.7	0.4	0.3
Newborn affected by maternal complications of pregnancy	1,655	1,309	1,328	4	4	5	0.4	0.3	0.3
Newborn affected by complications of placenta, cord, and membranes	975	962	932	3	3	3	0.2	(NA)	0.2
Accidents and adverse effects	930	787	726	2	3	3	0.2	(NA)	0.2
Infections specific to the perinatal period	875	788	815	2	3	3	0.2	(NA)	0.2
Pneumonia and influenza	634	492	400	2	2	1	0.2	(NA)	0.1
Intrauterine hypoxia and birth asphyxia	762	475	459	2	2	2	0.2	(NA)	0.1
All other causes	12,001	9,432	9,694	31	32	34	2.9	(NA)	2.5

Source: U.S. National Center for Health Statistics, *Vital Statistics of the United States*, Annual; *National Vital Statistics Reports (NVSR)* (formerly *Monthly Vital Statistics Report*); and unpublished data.

NOTES: Excludes deaths of nonresidents of the United States. Deaths classified according to ninth revision of *International Classification of Diseases*.

(NA) = Not Available *Deaths of infants under 1 year old per 1,000 live births.

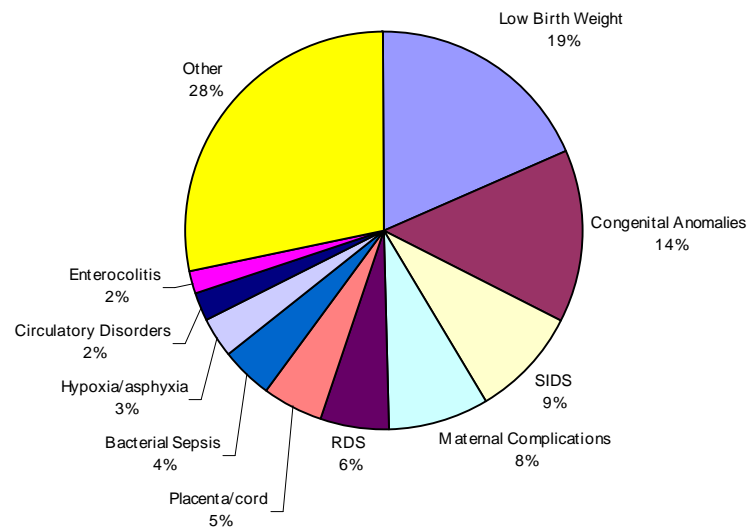
More recent information regarding infant deaths specific to Maryland for 2000 is shown in Figure 6. Low birth weight and congenital anomalies attributed to approximately one-third of the causes of infant death in 2000, 18.5 percent and 14.0 percent respectively. Table 31 shows that low birth weight ranked as the highest cause for infant mortality deaths for African American infants in 2000 while congenital anomalies ranked as the highest cause for white infants, 285.6 percent and 89.6 percent respectively. Cause-specific mortality rates were higher

³³ Ibid., P. 2

³⁴ Ibid., P. 2

for African American infants than white infants for all leading causes of death with the exception of circulatory disorders that were 12.2 percent for African American infants and 20.2 percent for white infants. Table 31 also reflects that six of the ten principal causes of infant death declined from 1999 to 2000. Low birth weight, congenital anomalies, sudden infant death syndrome (SIDS), respiratory distress syndrome (RDS), sepsis, and diseases of the circulatory system all showed increases during this period.

Figure 6. Distribution of Infant Deaths by the Ten Leading Causes: Maryland, 2000.



Source: DHMH, Vital Records Administration, Infant Mortality in Maryland 2000

Table 31
Infant Mortality Rates and Percent Change in Rates by Cause of Death and Race: Maryland, 1999 and 2000

2000 Rank	Cause of Death with 10 th Revision International Number	Number of Deaths		Mortality Rate*		Percent Change** 1999-2000
		1999	2000	1999	2000	
ALL RACES						
1	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	117	102	162.9	137.4	-15.9
2	Congenital malformations, deformations, and chromosomal abnormalities (Q00-Q99)	79	77	110.0	103.7	-5.7
3	Sudden infant death syndrome (R95)	56	49	78.0	66.0	-15.3
4	Newborn affected by maternal complications of pregnancy (P01)	33	44	45.9	59.3	29.0
5	Respiratory distress of newborn (P22)	31	31	43.2	41.8	-3.2
6	Newborn affected by complications of placenta, cord, and membranes (P02)	26	27	36.2	36.4	0.5
7	Bacterial sepsis of newborn (P36)	25	24	34.8	32.3	-7.1
8	Intrauterine hypoxia and birth asphyxia (P20-P21)	12	17	16.7	22.9	37.1
9	Diseases of the circulatory system (I00-I99)	18	12	25.1	16.2	-35.5
9	Necrotizing enterocolitis of newborn (P77)	10	12	13.9	16.2	16.1
	All other causes (residual)	189	155	263.2	208.8	-20.6
All Causes		596	550	829.8	741.0	-10.7
WHITE						
1	Congenital malformations, deformations, and chromosomal abnormalities (Q00-Q99)	30	40	69.1	89.6	29.6
2	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	37	28	85.3	62.7	-26.4
3	Sudden infant death syndrome (R95)	24	24	55.3	53.8	-2.8
4	Respiratory distress of newborn (P22)	10	16	23.0	35.9	55.6
5	Newborn affected by complications of placenta, cord, and membranes (P02)	6	13	13.8	29.1	110.7
6	Newborn affected by maternal complications of pregnancy (P01)	7	11	16.1	24.6	52.8
6	Intrauterine hypoxia and birth asphyxia (P20-P21)	7	10	16.1	22.4	38.9
8	Diseases of the circulatory system (I00-I99)	6	9	13.8	20.2	45.8
8	Bacterial sepsis of newborn (P36)	11	8	25.4	17.9	-29.3
10	Necrotizing enterocolitis of newborn (P77)	2	1	4.6	2.2	-51.4
	All other causes (residual)	83	51	191.3	114.3	-40.3
All Causes		223	211	513.9	472.8	-8.0
AFRICAN AMERICAN						
1	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	77	70	323.2	285.6	-11.6
2	Newborn affected by maternal complications of pregnancy (P01)	19	33	79.8	134.6	68.8
3	Congenital malformations, deformations, and chromosomal abnormalities (Q00-Q99)	44	32	184.7	130.6	-29.3
4	Sudden infant death syndrome (R95)	32	25	134.3	102.0	-24.1
5	Respiratory distress of newborn (P22)	16	15	67.2	61.2	-8.9
5	Bacterial sepsis of newborn (P36)	25	15	104.9	61.2	-41.7
6	Newborn affected by complications of placenta, cord, and membranes (P02)	14	14	58.8	57.1	-2.8
7	Necrotizing enterocolitis of newborn (P77)	8	10	33.6	40.8	21.5
8	Intrauterine hypoxia and birth asphyxia (P20-P21)	5	6	21.0	24.5	16.6
9	Diseases of the circulatory system (I00-I99)	12	3	50.4	12.2	-75.7***
	All other causes (residual)	97	99	407.2	403.9	-0.8
All Causes		349	322	1465.0	1313.8	-10.3

Source: DHMH, Vital Statistics Administration, *Infant Mortality in Maryland 2000*

* Per 100,000 live births, ** Percent change is based on the exact rates and not the rounded rates presented here, *** Rates in 1999 and 2000 are significantly different (p<.05).

d. Maternal Deaths

It is difficult to discuss infant mortality without considering maternal mortality. A commonly used definition of a pregnancy-related (maternal) death is one developed by the World Health Organization (WHO) as follows:

"A maternal death is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes."³⁵ Further, WHO subdivides maternal deaths into the following two groups:

"Direct obstetric deaths: those resulting from obstetric complications of the pregnancy stated (pregnancy, labor, and puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.

Indirect obstetric deaths: those resulting from previous existing disease that developed during pregnancy and which was not due to direct causes, but which was aggravated by physiologic effects of pregnancy."³⁶

According to a 1998 report released by the Centers for Disease Control and Prevention (CDC), in 1930, the national maternal mortality ratio (MMR) was 670 maternal deaths per 100,000 live births. During the 1940s and 1950s, the ratio substantially declined and continued to do so until 1982. Between 1982 and 1996, the annual maternal mortality ratio fluctuated between about 7 and 8 maternal deaths per 100,000 live births. (See Figure 7) During 1982-1996, trends by race were similar to the overall ratio, with no reductions observed for either African American or white women. Maternal mortality ratios remained higher for African American women than for white women; ratios for African American women fluctuated between 18 and 22 per 100,000 births while ratios for white women fluctuated between 5 and 6 per 100 lives births.³⁷ While the reason for the lack of improvement in maternal morality is not certain, during the same time period, infant mortality declined steadily because of advances in the survival of low birth weight and pre-term infants, and in the prevention of causes such as sudden infant death syndrome.³⁸

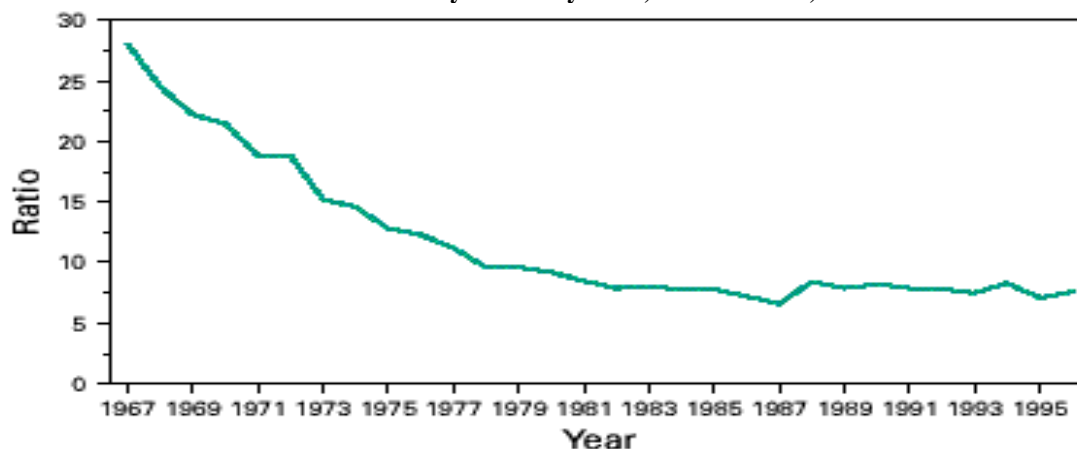
³⁵ Ibid, P. 143

³⁶ Ibid, P. 143

³⁷ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *Maternal Mortality-United States, 1982-1996*, Vol. 47, No. 34, September 4, 1998.

³⁸ Ibid., Editorial Note

Figure 7
Maternal Mortality Ratio* by Year, United States, 1967-1996



Source: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *Maternal Mortality, United States, 1982-1996*, Vol 47. No. 34, September 4, 1998.

*Number of maternal deaths per 100,000 live births. The term "ratio" is used instead of rate because the numerator includes some maternal deaths that were not related to live births and thus were not included in the denominator.

In a further study, the CDC focused on disparities in maternal mortality between African American and white women from 1987 to 1996.³⁹ In every state where MMRs could be reliably calculated, African American women were more like than white women to die from complications of pregnancy. MMRs were calculated using information from birth and death certificates filed in state vital statistic offices and compiled by CDC's National Center for Health Statistics. As shown in Table 32, total MMRs ranged from 1.9 (New Hampshire) to 22.8 (District of Columbia). MMRs for African American women in 26 states ranged from 8.7 (Massachusetts) to 28.7 (New York). For white women, MMR in 41 states ranged from 2.7 (Massachusetts) to 9.2 (Vermont). In every state where ratios could be calculated, the MMR for African American women was higher than for white women. For example, the African American: white ratio of MMRs ranged from 2.6 (California, Maryland, and South Carolina) to 6.3 (Michigan). With the exception of Massachusetts (3.1), New Hampshire (1.9), and Washington (3.3), the goal in achieving the Healthy People 2010 objective to reduce the maternal mortality ratio to no more than 3.3 (pregnancy-related deaths) per 100,000 live births has not been reached.

³⁹ The findings in the report are subject to limitations. For example, U.S. vital statistics data during 1987-1996 indicated that 3,086 women died because of pregnancy complications; however, these data are underestimates because of misclassification on death certificates. Additionally, misclassification of race on death certificates varies among the states or sometimes the information is not available.

Table 32
Maternal Mortality Ratios* (MMRs) for African American and White Women By State, United States, 1987-1996[†]

State	MMR		African American: White Ratio [§]	Total MMR	(95% CI [¶])	% Births to African American Women
	African American	White				
Alabama	21.1	6.7	3.1	11.7	(9.2-14.7)	34.0
Alaska	**	**	--	3.6**	(1.0- 9.2)	4.5
Arizona	**	4.0	--	5.2	(3.7- 7.2)	3.5
Arkansas	12.4 ^{††}	4.1 ^{††}	3.0	6.2	(3.9- 9.4)	22.9
California	17.9	6.9	2.6	8.1	(7.3- 8.8)	7.9
Colorado	**	6.5	--	6.9	(4.8- 9.4)	5.2
Connecticut	**	5.0	--	5.3	(3.4- 7.8)	12.5
Delaware	**	**	--	3.8**	(1.0- 9.7)	23.5
District of Columbia	25.7	**	--	22.8	(16.4-34.0)	77.7
Florida	24.8	5.3	4.7	9.7	(8.3-11.1)	23.1
Georgia	20.3	5.5	3.7	10.7	(8.8-12.7)	35.3
Hawaii	**	**	--	4.6 ^{††}	(2.5- 7.7)	5.7
Idaho	**	6.7 ^{††}	--	6.1 ^{††}	(3.3-10.2)	0.4
Illinois	21.3	4.3	5.0	7.5	(6.2- 8.7)	20.1
Indiana	13.3 ^{††}	4.0	3.3	4.5	(3.2- 6.1)	9.3
Iowa	**	5.6 ^{††}	--	5.1	(3.1- 7.9)	2.6
Kansas	27.3 ^{††}	5.2 ^{††}	5.2	6.3	(4.1- 9.3)	7.3
Kentucky	**	7.0	--	6.7	(4.7- 9.2)	8.4
Louisiana	18.9	6.2	3.0	11.7	(9.3-14.5)	41.3
Maine	**	**	--	6.3 ^{††}	(3.0-11.6)	0.5
Maryland	15.9	6.1	2.6	9.1	(7.1-11.5)	31.5
Massachusetts	8.7 ^{††}	2.7	3.2	3.1	(2.1- 4.6)	9.4
Michigan	22.6	3.6	6.3	7.5	(6.0- 8.9)	19.6
Minnesota	**	3.4 ^{††}	--	3.8	(2.5- 5.6)	4.1
Mississippi	20.5	5.1 ^{††}	4.0	12.3	(9.2-16.1)	47.4
Missouri	15.3 ^{††}	5.8	2.7	7.4	(5.6- 9.6)	16.4
Montana	**	**	--	3.5**	(1.0- 8.9)	0.3
Nebraska	**	3.2 ^{††}	--	3.4 ^{††}	(1.5- 6.7)	5.4
Nevada	**	5.9 ^{††}	--	6.4 ^{††}	(3.5-10.8)	8.9
New Hampshire	**	**	--	1.9**	(0.4- 5.4)	0.6
New Jersey	19.0	3.9	4.9	6.9	(5.4- 8.5)	19.1
New Mexico	**	7.0 ^{††}	--	9.5	(6.2-13.9)	1.9
New York	28.7	7.6	3.8	12.0	(10.7-13.3)	21.3
North Carolina	21.2	6.3	3.4	11.9	(9.8-14.1)	28.4
North Dakota	**	6.1 ^{††}	--	7.7 ^{††}	(3.1-15.8)	0.9
Ohio	16.8	4.5	3.7	6.3	(5.1- 7.6)	15.3
Oklahoma	18.4 ^{††}	4.6 ^{††}	4.0	6.2	(4.1- 8.9)	10.4
Oregon	**	3.6 ^{††}	--	4.6	(2.7- 7.1)	2.2
Pennsylvania	20.5	3.9	5.2	6.4	(5.2- 7.7)	14.7
Rhode Island	**	**	--	4.3**	(1.6- 9.3)	7.6
South Carolina	17.4	6.6	2.6	10.8	(8.2-14.0)	37.9
South Dakota	**	**	--	3.7**	(1.0- 9.4)	0.7
Tennessee	19.5	4.9	4.0	8.2	(6.3-10.6)	23.2
Texas	17.4	6.3	2.7	7.7	(6.8- 8.7)	13.1
Utah	**	4.5 ^{††}	--	4.3 ^{††}	(2.4- 7.0)	0.6
Vermont	**	9.2 ^{††}	--	9.1 ^{††}	(3.7-18.7)	0.3
Virginia	12.0	3.8	3.2	5.8	(4.4- 7.5)	23.8
Washington	**	3.0	--	3.3	(2.1- 4.8)	3.9
West Virginia	**	5.7 ^{††}	--	5.9 ^{††}	(3.2-10.2)	3.7
Wisconsin	16.2 ^{††}	3.9	4.1	5.3	(3.7- 7.3)	9.7
Wyoming	**	**	--	5.9**	(1.6-15.2)	1.0
Total	19.6	5.3	3.7	7.7	(7.4-8.0)	16.0

Source: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *State-Specific Maternal Mortality Among Black and White Women*, United States, 1987-1996, Vol. 48, No. 23, June 18, 1999.

* Maternal deaths per 100,000 live-born infants. CDC's National Center for Health Statistics uses the term "rate" when reporting this indicator of maternal mortality. The term "ratio" is used instead of rate in this report because the numerator includes some maternal deaths that were not related to live-born infants and thus were not included in the denominator.†n-3086.

§All ratios are significantly greater than 1.0 (p<0.02).

¶Confidence interval.

** Point estimates for states with fewer than seven maternal deaths for 1987-1996 are considered unreliable (relative standard error [RSE]: >38%).

††Point estimates for states with seven -19 maternal deaths for 1987-1996 are considered less reliable (RSE: 23%-38%) than estimates from states with >19 maternal deaths.

4. Quality Issues

Historically, Maryland's infant mortality rates have been higher than the nation's as a whole. According to Dr. Georges C. Benjamin, Maryland Secretary of Health and Mental Hygiene, factors contributing to higher mortality among black infants include "higher rates of poverty and inadequate access to health insurance, prenatal care, and proper nutrition."⁴⁰ Consequently, the state plans to launch a two-year \$800,000 multimedia ad campaign in January 2002 to illustrate the importance of early prenatal health care. Additionally, Maryland has increased women's access to health care by offering health insurance to uninsured pregnant women through the Maryland Children's Health Program.⁴¹ Maryland also has established a Governor's Commission on Infant Mortality to analyze factors contributing to infant mortality and develop strategies for reducing infant deaths.

In 1996, the University of Maryland Medical Center and the Johns Hopkins Children's Center formed a joint venture to transport and care for the region's newborns. Known as the Maryland Regional Neonatal Transport Program (MRNTP), the Program provides transportation of critically ill infants from community hospitals to centers that provide higher levels of specialized care. Physicians who need to transport a sick infant make a telephone call to consult with a pediatrician who specializes in newborn care from either the University of Maryland or Johns Hopkins. An ambulance is then sent, along with a neonatal transport nurse who makes certain that the infant is stabilized, and then the infant is transported.⁴² MRNTP provides transportation throughout the entire state of Maryland.

The MHCC is one of two State agencies that have adopted the Maryland Perinatal System Standards as regulations. The other agency is the Maryland Institute for Emergency Medical Services Systems (MIEMSS), which is also responsible for verifying a CON application's compliance with the Level III, III+, or IV standards. Otherwise, MIEMSS performs this process for only those hospitals that wish to accept referrals from other hospitals for the provision of comprehensive perinatal services.

5. Future Utilization of NICU Services

Although recent figures suggest that Maryland's infant mortality rate and low birth rates are decreasing, there are various factors that must be considered when projecting the need for NICU services. These include: (1) risk factors that affect low birth weight, neonatal mortality, and maternal mortality, (2) demographics of the region, (3) supply and distribution of specialized health care personnel, and (4) methods for paying for NICU services. While advances in medical care have assisted in reducing infant mortality, state and local health departments, and private caregivers, must continue to make families aware of the importance of perinatal care in order to further reduce the need of NICU services.

⁴⁰ *State's Infant Death Rate Hit All-Time Low in 2000*, The Sun, July 26, 2001.

⁴¹ Ibid.

⁴² University of Maryland Medical News, *Maryland Regional Neonatal Program to be Taken Over by the UM Medical Center and Hopkins Children's Center*, 1996, WEBSITE: <http://www.um.edu>

D. Burn Care Services

1. Definition

The third specialized service examined in this Working Paper, burn care services, was also added to the services regulated by CON in 1988. According to CMS, "A burn care unit provides care to severely burned patients that are of a more intensive nature than the usual acute nursing care provided in medical surgical units. Burn Care Units shall be staffed with specially trained nursing personnel and contain specialized support equipment for burn patients who require intensified, comprehensive observation and care."⁴³

2. Supply and Distribution of Burn Care Services

Currently, Johns Hopkins Bayview Medical Center's Baltimore Regional Burn Center (BRBC) is the sole burn treatment center in the state of Maryland. BRBC manages 275 to 300 inpatients per year. Of these patients, 25 percent are children. Approximately 495 emergency service patients are treated as outpatients and released from the facility. Because follow-up care is vital for burn victims, the outpatient burn clinic staff sees approximately 1,800 patients per year for follow-up treatment. BRBC maintains its own emergency service and currently has the following number of rooms/beds:⁴⁴

- Ten intensive care private rooms
- Ten intermediate step-down beds
- Five beds in the pediatric unit

Located in the District of Columbia, the Burn Center at the Washington Hospital Center serves as the adult regional burn center for DC, southern Maryland, and northern Virginia. The Center features a seven-bed intensive care unit, a ten-bed intermediate/rehabilitation care unit, and a burn rehabilitation therapy department. In Fiscal Year 2000, the Center admitted 383 acute burn patients. A total of 160 patients (42 percent) of these patients suffered flame-related burns and 24 patients (6.2 percent) died as a result of their burn injuries.⁴⁵

3. Trends in the Utilization of Burn Care Services

According to the American Burn Association, each year in the United States, 1.25 million burn injuries require medical attention. Approximately 50,000 of these patients require hospitalization and approximately half of those burn patients are admitted to a specialized burn unit. Of these patients, approximately 4,500 die. Serious complications often follow a burn incident and up to 10,000 people in the United States die every year of a burn-related infection. The most common infectious complication among hospitalized burn patients is pneumonia.⁴⁶

⁴³ WEBSITE: <http://www.hcfa.gov/medicaid/stateplan/state%5fdata>

⁴⁴ Johns Hopkins Bayview Medical Center, *The Baltimore Regional Burn Center*, WEBSITE: <http://www.jhbm.jhu.edu>

⁴⁵ Ibid.

⁴⁶ National Institute of General Medical Sciences (NIGMS), *Trauma, Burn, Shock, and Injury: Facts and Figures*, WEBSITE: <http://www.nigms.nih.gov/news/facts>

In Maryland during Fiscal Year 2000, patients were admitted to BRBC from each of the state's 23 counties as well as Baltimore City. Baltimore City had the largest percentage of patients admitted with 89 patients (32.2 percent), followed by Baltimore County with 63 patients (22.8 percent). Patients were also admitted from the surrounding areas of Delaware, Virginia, West Virginia, and Pennsylvania. Of the 276 patients admitted to BRBC, 147 (53.3 percent) received care as a result of flame burns.⁴⁷ The following table shows the breakdown of burn types that were treated at BRBC during Fiscal Year 2000:

Table 33
Admission to Baltimore Regional Burn Center by Type of Burn: Maryland, Fiscal Year 2000

Type of Burn	Patients	Percentage
Flame	147	53.3
Scald	92	33.3
Electrical	11	4.0
Contact	10	3.6
Chemical	5	1.8
TENS	9	3.3
Sunburn	0	0.0
Frostbite	2	0.7
Radiation	0	0.0

Source: MIEMSS, 1999-2000 Annual Report

Admissions to BRBC are usually via ambulance. As shown in Table 34, approximately 75 percent of patients during Fiscal Year 2000 arrived at BRBC by ambulance:

Table 34
Admissions to Baltimore Regional Burn Center by Mode of Transport: Maryland, Fiscal Year 2000

Mode of Transportation	Patients	Percentage
Ambulance	205	74.3
Helicopter	37	13.4
Other	34	12.3

Source: MIEMSS, 1999-2000 Annual Report

Of the 276 admissions to BRBC in Fiscal Year 2000, over 75 percent were adults. Less than five percent of the total admissions resulted in death. Additional statistics are summarized in the following table:

⁴⁷ Maryland Institute for Emergency Medical Services Systems, 1999-2000 Annual Report, WEBSITE: <http://miemss.umaryland.edu/2kAnRpt>

Table 35
Baltimore Regional Burn Center Statistical Summary: Maryland, Fiscal Year 2000

Statistic	Number	Percent
Admissions	276	
Adults	208	75.36%
Children	68	24.63%
Average Age	36.07 Years	
Average Total Burn Surface Area	11.68	
Average Length of Stay	9.04 Days	
Inhalation Injury	35	12.7%
Mortality	12	4.3%

Source: MIEMSS, 1999-2000 Annual Report

4. Research and Education

Improving methods of wound healing and tissue repair offer opportunities to enhance the quality of life for burn patients. Scientists are currently investigating ways to treat wounds caused by burns with new drugs or biological agents such as skin growth factors.⁴⁸ Recently, the BRBC has been growing cultured skin from samples taken from patients and the Center maintains its own research laboratory for that purpose. In its goal to provide patients with excellent burn care, BRBC is committed to burn prevention, as well as to community and professional education. Hospital-based personnel, such as doctors, nurses, and technicians, as well as paramedics and emergency medical technicians, are offered professional education. The Burn Center is also involved in providing pre-hospital education that includes participating in case reviews, speaking and teaching at individual fire companies, and serving as a clinical rotation site for paramedical training programs. Additionally, prevention educational activities have increased in the general community. For example, BRBC is currently working with the Maryland Fire Marshal's Office regarding prevention issues.⁴⁹

In conjunction with BRBC, the Baltimore Regional Center for Burn Reconstruction (BRCBR) was developed in 1990 to formalize a program of rehabilitation and reconstruction for burn survivors. In an effort to provide outpatient burn survivors with education regarding reconstruction and rehabilitation care, BRCBR provides services such as occupational therapy, physical therapy, and social service programs.⁵⁰

5. Quality Issues

Several mechanisms are available to evaluate the process of burn care in order to review outcome and assist in quality of care. According to the American Burn Association, audit filters are one way to examine the delivery of care and to identify potential patient care problems regarding burn victims. The audit filters used by burn centers should be constructed to examine

⁴⁸ National Institute of General Medical Sciences (NIGMS), *Trauma, Burn, Shock, and Injury: Facts and Figures*, WEBSITE: <http://www.nigms.nih.gov/news/facts>

⁴⁹ Johns Hopkins Bayview Medical Center, *The Baltimore Regional Burn Center*, WEBSITE: <http://www.jhbmc.jhu.edu>

⁵⁰ Ibid.

the "timeliness, appropriateness, and effectiveness of care."⁵¹ Examples of such audit filters are shown below:

- Appropriateness of pre-hospital fluid and airway management
- Need for emergency airway management during resuscitative phase
- Volume of resuscitation fluid required for first 24-hour resuscitation
- patients with resuscitation failure
- Time to first excision an grafting procedure
- Major complications subcategorized by organ system
- Infectious complications
- Graft take less than 80 percent
- Adequacy of nutritional supplementation
- Ventilator days
- ICU days
- Total hospital day
- Readmission for unexpected problems
- Mortality
- Need for reconstruction procedures
- Return to work

Additionally, the American Burn Association believes that patient care conferences should be held on a weekly basis to access and evaluate the status of each burn patient that has been admitted to a burn center facility.⁵²

6. Cost of Burn Care Services

Severe burn injuries affect both physical and psychological functioning. Due to these changes in function, burn injury can lead to impairment, disability, and handicap. Additionally, high-risk burn patients require complex pharmaceutical therapy, as well as ongoing assessment of drug regimens.⁵³ A burn of 30 percent of total body area can cost as much as \$200,000 in initial hospitalization costs and for physicians fees.⁵⁴ In addition, the cost of rehabilitation and the loss of the patient's productive work time must also be taken into consideration.

7. Future Utilization of Burn Care Services

The establishment of burn care services requires CON approval under the current Maryland health planning law. Although there is only one burn care facility in Maryland, there are approximately 200 special burn care centers throughout the United States. Only during the past several years have those in the medical profession begun to recognize and understand the

⁵¹ American Burn Association, *Qualify of Care Assessment*, WEBSITE: <http://www.ameriburn.org>

⁵² Ibid.

⁵³ The Phoenix Society for Burn Survivors-Newsletter, *How Long does it Take to Return to Work after Burn Injury?*, Fall/Winter, 1999.

⁵⁴ Burn Free, *Burn Facts*, October 12, 2000.

problems associated with burns.⁵⁵ Last year, the Coalition for American Trauma Care supported a \$100 million fire bill that cleared the U.S. House of Representatives. The bill included \$10 million for burn safety programs, burn research in burn center hospitals, and after-burn treatment and counseling.⁵⁶

⁵⁵ Burns and Burn-Survivor Information, *Burn Facts*, WEBSITE: <http://www.burns-injury-burn-accidents.com>

⁵⁶ A.A.S.T. Webnet Domain, *The Coalition for American Trauma Care Washington Report*, Vol. 2, No. 7, April 6, 2000. WEBSITE: <http://www.aast.org>

III. GOVERNMENT OVERSIGHT OF ORGAN TRANSPLANT SURGERY NEONATAL INTENSIVE CARE SERVICES, AND BURN CARE IN MARYLAND

Government oversight of organ transplant surgery, neonatal intensive care services, and burn services including facilities, staff, and program operation is the responsibility of both federal and state agencies. Although this report focuses on the oversight responsibilities of the MHCC, it is important to consider how organ transplant surgery, neonatal intensive care services, and burn services are regulated by other government agencies. Listed below is a summary of the primary federal and state agencies that provide oversight at some level or over some aspect of the provision of these three types of services in Maryland.

A. Federal Level

1. Centers for Medicare and Medicaid Services (CMS)

Formerly known as HCFA, CMS is a federal agency under the Department of Health and Human Services that administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). Under the reorganization of the agency, there are three new centers of service. The Center for Beneficiary Choices focuses on the Medicare+Choice program and provides beneficiaries with information they need to make choices. The Center for Medicare Management centers on the traditional fee-for-service program, dealing with providers. The Center for Medicaid and State Operation focuses on such programs as Medicaid, SCHIP, and insurance regulation administered by states. In addition to providing health insurance, CMS also performs a number of quality-focused activities, including regulation of laboratory testing, surveys and certification of health care facilities, and quality of care improvement.

2. Office of the Inspector General

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) works with CMS to develop and implement recommendations to correct systemic vulnerabilities detected during OIG/HHS investigations. The OIG believes that an effective compliance program provides a mechanism that brings the public and the private sectors together to reach mutual goals of reducing fraud and abuse, improving the quality of health care services and reducing the cost of health care.⁵⁷

3. Department of Veterans Affairs

The Department of Veterans Affairs (VA) administers laws providing benefits and other services to veterans, their dependents, and the beneficiaries of veterans. The VA has joined the nationwide efforts of national and local organizations to expand the number of persons in the United States willing to donate organs and tissue for transplantation. In 2000, VA Transplant Centers had approximately 380 veterans who were included on the national organ transplant

⁵⁷ *Office of Inspector General's Compliance Program Guidance for Hospices*, September 1999, p.3.

waiting list. The VA provides guidance to all VA medical centers nationwide regarding organ, tissue, and eye donation within VA facilities. VA Transplant Centers have offered solid organ transplant services since 1962 and bone marrow transplant services since 1982. The Centers, which are located across the country, perform over 250 transplants a year.⁵⁸

4. Organ Procurement Organizations

In the Maryland region, two OPOs cover the regional service areas, namely The Transplant Resource Center of Maryland (TRC) and the Washington Regional Transplant Consortium (WRTC). TRC is a not-for-profit health service organization that provides organ procurement and tissue bank services to the citizens of Maryland. TRC was incorporated in 1991, consolidating the former Maryland Organ Procurement Center and the Maryland Tissue Bank. The federal Centers for Medicare and Medicaid Services (CMS) certifies TRC as an organ procurement organization (OPO), and the State of Maryland licenses TRC as a tissue bank.

The CMS' current certification process sets performance standards for certifying OPOs based on donors per million of population in their service areas. Without CMS certification, an OPO cannot receive Medicare and Medicaid payments, nor continue to operate. The process of certification of OPOs is currently being reviewed under the Organ Procurement Organization Certification Act of 2000.

5. Transplant Resource Center of Maryland (TRC)

The Transplant Resource Center of Maryland is a not-for-profit health service organization that provides organ procurement and tissue bank services to the citizens of Maryland. TRC was incorporated in 1991, consolidating the former Maryland Organ Procurement Center and the Maryland Tissue Bank. Centers for Medicare and Medicaid Services certifies TRC as an organ procurement organization (OPO), and the state of Maryland licenses TRC as a tissue bank. TRC provides tissue for thousands of tissue transplant surgeries. While most of the skin TRC recovers is used to help people survive severe burns, a portion goes to Maryland hospitals for wound care procedures, or is sent to out-of-state facilities for emergency procedures. Some of the ways tissue donation helps people enhance their lives is through spinal fusions, hip replacements, limb reconstruction, knee replacements, and facial and cranial reconstructions.⁵⁹

6. Organ Procurement and Transplantation Network

UNOS, under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services (HHS), operates the Organ Procurement and Transplantation Network (OPTN). The OPTN was established with the passage of the 1984 National Organ Transplant Act and is regulated by HHS. The role of the OPTN is to improve the effectiveness of the nation's organ procurement, distribution, and transplantation systems by

⁵⁸ Department of Veterans Affairs, National Transplant Program, WEBSITE: <http://www.trioncac.org/vatransplantprog.html>

⁵⁹ Transplant Resource Center of Maryland, WEBSITE: <http://www.mdtransplant.org/orc.htm>

increasing the availability of, and access to, donor organs for patients with end-stage organ failure; to develop, implement, and maintain quality assurance activities; and to systematically gather and analyze data and regularly publish the results of the national experience in organ procurement and preservation, tissue typing, and clinical organ transplantation. Institutional members of UNOS, including transplant centers and independent organ procurement organizations, must meet specific membership criteria.

B. State Level

1. Department of Health and Mental Hygiene

The Department of Health and Mental Hygiene (DHMH) develops health programs that protect Maryland residents. It is a highly complex organization with a broad scope of responsibility. DHMH is comprised of over 30 program administrations, 24 local health departments, over 20 residential facilities and more than 20 health professional boards and commissions. The Medical Assistance Program (Medicaid), which pays for organ transplant surgery, NICU, and burn services, is also located within DHMH.

a. Office of Health Care Quality

The Office of Health Care Quality (OHCQ), an administration within DHMH, is responsible for monitoring the quality of care and compliance with both state and federal regulations for hospitals and other health-related facilities in Maryland. OHCQ is responsible for licensing, certifying, and/or approving providers who provide care and services. The agency also investigates quality of care complaints from the general public. OHCQ is also responsible for licensing dialysis centers that are often utilized by patients awaiting kidney transplants.

b. Kidney Disease Program (KDP)

Formed in 1971, the Program financially assists Marylanders who are certified end-stage renal disease patients. This assistance for treatment is available only after all other medical and federal insurance coverage has been pursued. Since the KDP is the payer of last resort, it does not have its own fee schedule. Approximately 95 to 98 percent of KDP certified beneficiaries qualify for Medicare. If the beneficiary has no other source of insurance such as Medical Assistance or private health insurance, the KDP will pay the Medicare deductible for the hospital bill. In addition, physician, laboratory, and other medical claims are also submitted to the Program after Medicare, Medicaid, and private insurance. If a KDP beneficiary has no health insurance other than KDP, the KDP will reimburse the provider at Maryland Medical Assistance rates. The KDP does not reimburse for any transplants other than kidney.⁶⁰

c. Pharmacy Assistance Program

Authorized in 1978, the Program helps pay for certain kinds of maintenance prescription drugs for chronic conditions; anti-infective drugs, including AZT; and insulin syringes and

⁶⁰ Electronic mail communication from Barbara Bradford, Division Chief, DHMH, August 28, 2001.

needles. Completely state-funded, the Program is designed for low-income families and individuals who are not eligible for Medicaid (Code Health - General Article, sec. 15-124).

d. Public Health Administration

The Prevention and Disease Control unit of the Community and Public Health Administration is primarily concerned with the prevention of disease and injury in Maryland through education and preventive health services, including diseases related to the heart and lung that often require organ transplants. Also under this Administration, the Maryland WIC Program provides health supplemental foods and nutrition counseling for pregnant women, new mothers, infants, and children under age five.⁶¹ The Division of Maternal and Perinatal Health is another program under the Public Health Administration that offers a Preconception Health Program, a Pregnancy Risk Assessment Monitoring System, and an Improved Pregnancy Outcome Program.⁶²

2. Health Professionals Boards & Commissions

The purpose of the Health Professionals Boards & Commissions is to ensure that the highest quality health care is provided to the residents of Maryland. The Health Professionals Boards & Commissions issues licenses to practice in the state of Maryland. It also investigates complaints and takes disciplinary action against licensees when necessary. Both health professionals and consumer members serve on the boards. Each board follows the ethical guidelines and standards of the profession it regulates. Another function of the Health Professionals Boards & Commissions is to promote knowledge and performance of goals for professionals that concern the citizens of the state of Maryland.

The Commission on Kidney Disease establishes physical and medical standards for the operation of dialysis and renal transplant centers and sets standards for the acceptance of patients into the treatment phase of the program. Additionally, the Commission institutes and supervises educational programs for the public and health providers for the prevention and treatment of chronic renal disease. The Commission evaluates the kidney disease program and submits an annual report to the Governor.

One health occupation board, the Board of Physician Quality Assurance (BPQA), is an agency of the state with the authority to license physicians and certain other health care professionals such as physician assistants, cardiac rescue technicians, and medical radiation technologists in Maryland. In addition to establishing qualifications for licensure, the BPQA is responsible for investigating complaints against licensed professionals and for taking action against the license of those who violate Maryland's standards of medical care delivery. This would include care delivered by medical professionals in connection with organ transplant surgery, NICU, and burn care services.

⁶¹ WEBSITE: <http://mdwic.org>

⁶² WEBSITE: <http://mdpublichealth.org>

The missions of other boards, such as the Board of Nursing, the Board of Social Workers, and the Board of Pharmacy are to protect the people of Maryland through licensure, certification, and other regulations governing the scope and details of each health occupation's practices.

3. Maryland Institute for Emergency Medical Services Systems (MIEMSS)

Governed by the State Emergency Medical Services Board, MIEMSS is an independent agency that is responsible for coordinating all emergency medical services in Maryland. MIEMSS oversees and coordinates all components of the statewide Emergency Medical Service (EMS) system including planning, operations, evaluation, and research. Additionally, it operates and maintains a statewide communications system, designates trauma and specialty centers, provides leadership and medical direction, conducts and/or supports EMS educational programs, licenses and regulates commercial ambulance services, and participates in EMS-related public education and prevention programs.⁶³ MIEMSS has also established a Perinatal Advisory Committee to make recommendations of MIEMSS concerning issues related to transport, outcomes, and other indicators of quality, the process of designation, and the collection of data.

4. Maryland Insurance Administration

The Maryland Insurance Administration (MIA) provides for the licensure of insurers and agents. In doing so, it establishes financial and capital standards for insurers of all types, and sets requirement for rate making and disclosure, and of fair practices. The MIA also handles consumer complaints regarding coverage decisions and appeals of medical necessity decisions made by HMOs or insurers. With respect to NICU services, the MIA assures that health plans offered by carriers operating in Maryland provide reasonable geographic accessibility to risk-appropriate perinatal services for their members who require such services.

5. Health Services Cost Review Commission (HSCRC)

The Health Services Cost Review Commission is authorized by state law to set the rates that all acute general, private psychiatric hospitals, and specialty hospitals may charge for inpatient services. Initially, the HSCRC determines a hospital's rates through the application of a rate review methodology, after which it uses a peer group evaluation to determine the reasonableness of a hospital's projected expenses. Adjustments may then be made to reflect the individual hospital's uncompensated care and payer mix. After a hospital's rates have been established, the hospital will usually receive an annual increase to its rates for inflation. Hospitals have some flexibility regarding the fees they charge for services. For example, a hospital may voluntarily charge less than its HSCRC-approved NICU rate by banking revenue in the NICU cost center and recovering the revenue in the future. Conversely, it may reduce charges and choose not to recover the revenue.

6. Maryland Health Care Commission

Through its statutory authority and responsibilities under Part II (Health Planning and Development), Subtitle 1 (Health Care Planning and Systems Regulation), of Article 19 (Health

⁶³ MIEMSS: *Mission/Vision/Key Goals*, Website: <http://miemss.umaryland.edu/2kAnRpt>

Care Facilities) of Maryland's Annotated Code, the MHCC is responsible for the development and administration of the State Health Plan. In turn, the State Health Plan provides the policies, review standards, and need projections against which applications for Certificate of Need are evaluated. Consequently, the SHP is fundamentally a policy and procedural guidebook for Commission decisions on the establishment and activities of health care providers and services defined by law⁶⁴ as "health care facilities" requiring CON review and approval.

Through the CON program, the Commission regulates market entry and, in many cases, exit from the market by these health care facilities, determines whether they may establish or close individual medical services⁶⁵, and may review proposals to expand or reduce service capacity. Certificate of Need as a regulatory tool has three levels:

- **Certificate of Need** – granted by the Commission based on an analysis and recommendation of applications, evaluated against the six general review criteria in CON procedural regulations at COMAR 10.24.01.08G(3), and the policies, standards, and need projections contained in the applicable section of the State Health Plan.
- **Exemption from CON** - a finding by the Commission "in its sole discretion," based on statutory criteria, that a proposed project is "not inconsistent with" the State Health Plan, will result in the more "efficient and effective" delivery of health care services, and is "in the public interest."
- **Determination of Coverage** – a determination in response to a written notice or request from a person or a health care facility issued by the Commission's Executive Director, that a proposed project is, or more often is *not* required to obtain a CON to undertake a given action, based on an analysis of existing law and regulation.

Organ Transplant

A CON is required for all new transplant programs. In order to be granted CON approval by the Commission, proposed new organ transplant programs must demonstrate consistency with the standards for CON review under COMAR 10.24.15 and address the general review criteria in the CON procedural regulations. Under CON law, organ transplant programs have been specified as a covered service under Specialized Health Care Services since July 1, 1988. A transplant program qualifies as a Maryland provider through one following options: (1) the program was established and operating prior to July 1, 1988; (2) the provider received a CON for that transplant program; (3) the provider received a determination issued by the Commission that

⁶⁴ The statute defines "health care facilities" for purposes of CON review at Health-General Article §19-114(e), and delineates the actions by proposed or existing health care facilities that require CON review and approval at §19-123.

⁶⁵ A list of the "medical services" regulated by the Commission was added to statute in 1988: "(1) Medicine, surgery, gynecology, addictions; (2) Obstetrics; (3) Pediatrics; (4) Psychiatry; (5) Rehabilitation; (6) Chronic care; (7) Comprehensive care; (8) Extended care; (9) Intermediate care; or (10) Residential treatment; or . . . [a]ny subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of health care services for which need is projected in the State health plan." Health-General Article §19-123(a)(4).

the program did not require a CON; (4) transplant programs that were existing, operating and performing transplant procedures prior to May 19, 1998 or transplant programs that were substantially under development, but not established and operating, prior to May 19, 1998 may be grandfathered as recognized Maryland providers if they provide the required information.

To promote effective planning for specialized services through a higher standard of quality for organ transplant services, the Commission establishes the following policies under the SHP:

- An organ transplant program should perform a minimum number of procedures annually, as defined by this plan. New transplant programs should achieve minimum volume standards within 36 months of beginning operation, and maintain the minimum utilization level in each subsequent year of operation.
- A new organ transplant program should not be established if it would interfere with the ability of existing programs to maintain at least the threshold volumes defined by this chapter.
- Fewer organ transplant services operating at higher volumes are preferable to more programs at threshold or minimum volumes.

NICU Services

As with organ transplant surgery, a CON is required for all new NICU programs in the State of Maryland. Under COMAR 10.24.18, the Commission will approve a new NICU only if an applicant demonstrates compliance with the Level III, III+, or IV perinatal system standards. The applicant must also demonstrate that the unit can sustain an average daily census of at least six critically ill patients or show evidence as to why this rule should not apply. A hospital applying to establish a new NICU will also be required to negotiate a revenue-neutral agreement within HSCRC. If, during a comparative review of applications in which all applicant have met all policies and standards, the Commission will give preference to the applicant with an established program to prevent low birth weight and infant mortality with particular outreach to minority and indigent patients in the hospital's regional service area.

Burn Care Services

The establishment of burn care services also requires CON approval. Because there is no State Health Plan chapter addressing burn care, proposals to establish new programs would be considered according to the following six general review criteria, found in the CON procedural regulations at COMAR 10.24.01.08G(3):

- That a proposed project *meets "all relevant State Health Plan standards, policies, and criteria"*;
- That proposed *new facilities or services are needed*, according either to a statistical need projection adopted by the Commission, or as demonstrated by a

quantitative analysis of need provided by the applicant, which documents an "unmet needs of the population to be served," and supports the ability of the proposed project to meet those needs;

- That the proposed project represents *a more cost-effective means of providing a proposed service*, as compared to existing facilities or health providers, or as compared to competing applicants for the same service in a comparative review;
- The proposed new facilities or services they proposed are viable, because *both the financial and the "non-financial" resources - such as community support and appropriate levels of needed professional and support staff - are available* at a level sufficient to implement the project within the prescribed time frames, and to sustain the facility or service once established;
- That the applicant or existing health care provider has met all of *the conditions applied to previous Certificates of Need*, and any commitments made that resulted in a preference in a previous CON review, if applicable; and
- That the proposed new facility or service will not have an unduly negative *impact on existing providers of the health care service in the same service area*, including the potential impact on "geographic and demographic access to services, on occupancy where there is a risk that [a new provider] will increase costs to the health care delivery system, and on the costs and charges of other providers."

IV. MARYLAND'S CERTIFICATE OF NEED REGULATION OF ORGAN TRANSPLANT SURGERY, NEONATAL INTENSIVE CARE SERVICES, AND BURN SERVICES COMPARED WITH OTHER STATES

The Commission surveyed other states and the District of Columbia to request information about the CON regulation of organ transplant, neonatal intensive care services, and burn services. In July 2001, the Commission mailed a questionnaire to those states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, published by the American Health Planning Association, as covering one or more of the above services by CON. Staff also searched State files by computer, and once again utilized the AHPA's electronic bulletin board service of state CON and other majority health regulatory programs to collect specific additional information. The following tables summarize the information that was provided.

Organ Transplant Services

Table 36
Status of CON Regulation of Organ Transplant Services by State, October 2001

Organ Transplant Covered (21)	CON Program Organ Transplant Not Covered (15)	No CON Program (15)
Alabama Alaska Connecticut District Of Columbia Florida Hawaii Illinois Iowa Kentucky Maine Maryland Massachusetts Michigan New Jersey New York North Carolina Rhode Island Vermont Virginia Washington West Virginia	Arkansas Delaware Georgia Mississippi Missouri Montana Nebraska Nevada New Hampshire Ohio Oklahoma Oregon South Carolina Tennessee Wisconsin	Arizona (1985) California (1987) Colorado (1987) Idaho (1983) Indiana (1998) Kansas (1985) Louisiana Minnesota (1984) New Mexico (1983) North Dakota (1995) Pennsylvania (1996) South Dakota (1988) Texas (1985) Utah (1984) Wyoming (1985)

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

Table 37
Summary of Regulation in States with CON Coverage for Organ Transplant Services, October 2001

State	CON	SHP	Legislation	Other
Alabama	✓	✓		No state health plan or specific CON regulations SHP chapters currently being developed
Alaska	✓			
Connecticut	✓			
District Of Columbia	✓			
Florida	✓			
Hawaii	✓		✓	
Illinois	✓		✓	
Iowa	✓			
Kentucky	✓	✓	✓	
Maine	✓			
Maryland	✓	✓	✓	
Massachusetts	✓			
Michigan	✓			
New Jersey	✓		✓	
New York	✓			
North Carolina	✓	✓	✓	Laws and Rules
Rhode Island	✓		✓	
Vermont	✓			
Virginia	✓	✓		
Washington	✓			
West Virginia	✓	✓		Regulated if new service with annual operating expenses above \$300,000

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

NICU Services

Table 38
Status of CON Regulation of Neonatal Intensive Care Services by State, October 2001

CON Program		No CON Program (15)
Neonatal Intensive Care Covered (24)	Neonatal Intensive Care Not Covered (12)	
Alabama		
Alaska		
Connecticut		
District of Columbia		
Florida		
Georgia		
Hawaii		
Illinois		
Kentucky		
Maine		Arizona (1985)
Maryland		California (1987)
Massachusetts		Colorado (1987)
Michigan	Arkansas	Idaho (1983)
Missouri	Delaware	Indiana (1998)
New Jersey	Iowa	Kansas (1985)
New York	Mississippi	Louisiana
North Carolina	Montana	Minnesota (1984)
Rhode Island	Nebraska	New Mexico (1983)
South Carolina	Nevada	North Dakota (1995)
Tennessee	New Hampshire	Pennsylvania (1996)
Vermont	Ohio	South Dakota (1988)
Virginia	Oklahoma	Texas (1985)
Washington	Oregon	Utah (1984)
West Virginia	Wisconsin	Wyoming (1985)

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

Notes: The list of states that have a CON program but do not regulate neonatal intensive care services is based on information published by the American Health Planning Association. Of the states that regulate neonatal intensive care services, Washington did not respond to the survey distributed by the Maryland Health Care Commission. Maine requires a CON for a new service or an addition to licensed beds. In Missouri, a CON is required for the service if the cost to develop it exceeds either the capital cost or equipment cost expenditure minimum of \$1 million. After January 1, 2002, the service will not be subject to CON unless it requires the acquisition of major medical equipment costing more than \$1 million. Vermont regulates neonatal intensive care services that are new services with annual operating expenses above \$300,000.

Table 39
Designation of Neonatal Intensive Care Services, October 2001

State	Numerical Designation	Other Descriptive Designation
Alabama	Level III	
Alaska	Level III	
Connecticut		
District of Columbia		
Florida	Level II, III	
Georgia	Level III	Subspecialty, Regional
Hawaii	Level II, III	
Illinois		
Kentucky	Level III	
Maine		
Maryland	Level III, III+, IV	
Massachusetts		Regional
Michigan		
Mississippi	Level III	
Missouri		
New Jersey		Regional
New York		Regional
North Carolina	Level III	
Rhode Island		
South Carolina	Level III	Regional
Tennessee		
Vermont		
Virginia	Level III	Regional
Washington		
West Virginia	Level II, III	
Total	12	6

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

Notes: Of the states that regulate neonatal intensive care services, Washington did not respond to the survey distributed by the Maryland Health Care Commission. The Guidelines for Perinatal Care, Fourth Edition, developed by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists, define specialty care, in part, as care of preterm infants with a birth weight of 1,500 grams or more. Subspecialty care includes the provision of comprehensive perinatal care services for all risk categories of mothers and neonates. A number of states identified Regional Perinatal Centers separately.

Table 40
Planning and Regulation of Neonatal Intensive Care Services, October 2001

State	State Health Plan	Certificate of Need Rules	Volume Standards	Unit Size
Alabama	X			
Alaska			X	
Connecticut				
District of Columbia		X		
Florida		X	*	X
Georgia	X	X	*	
Hawaii	X	X	*	X
Illinois		X		
Kentucky	X	X	*	
Maine		X		
Maryland	X	X	X	
Massachusetts		X	*	X
Michigan		X		X
Mississippi	X			X
Missouri		X		
New Jersey		X	X	X
New York		X	*	X
North Carolina		X		
Rhode Island		X	*	
South Carolina	X	X	*	X
Tennessee	X	X		X
Vermont	X	X		
Virginia	X	X		X
Washington				
West Virginia	X	X	*	
Total	11	20	3	10

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

Notes: Of the states that regulate neonatal intensive care services, Washington did not respond to the survey distributed by the Maryland Health Care Commission. The District of Columbia is developing a State Health Plan. Maine and Vermont reported that the planning document is not used to review CON proposals. Florida has adopted minimum occupancy rates for the approval of new or additional NICU beds. Georgia and Hawaii require a minimum aggregate or overall occupancy rate prior to approval of new or expanded services. Kentucky requires a minimum utilization rate for the approval of additional beds. Massachusetts has established an occupancy rate for the expansion of existing NICUs. New York requires neonatal special care units to have a minimum average annual occupancy rate. Rhode Island has proposed minimum volume standards for licensing hospitals that operate a NICU. South Carolina and Virginia have established minimum occupancy rates for units. West Virginia requires a minimum average occupancy rate for neonatal intensive care units.

States that have adopted licensing regulations for neonatal intensive care services include New Jersey, Rhode Island (proposed), and Pennsylvania. Ohio has adopted health care service quality rules for levels of obstetric and newborn care services. States without CON programs, or CON regulation of neonatal intensive care services, have used other strategies to encourage and support perinatal regionalization. For example, the California legislature mandated the

development of a statewide network of perinatal regionalization. (Available from http://www.perinatal.org/rppc_nar.shtml.)

Burn Services

Table 41
Status of CON Regulation of Burn Care Services by State, October 2001

CON Program		
Burn Care Covered	Burn Care Not Covered	No CON Program (15)
Alaska		
Connecticut		
District of Columbia		
Florida	Alabama	
Georgia (?)	Arkansas	Arizona (1985)
Hawaii	Delaware	California (1987)
Illinois	Iowa	Colorado (1987)
Kentucky	Massachusetts	Idaho (1983)
Maine	Michigan	Indiana (1998)
Maryland	Mississippi	Kansas (1985)
New Hampshire	Missouri	Louisiana
New Jersey	Montana	Minnesota (1984)
New York	Nebraska	New Mexico (1983)
North Carolina	Nevada	North Dakota (1995)
Rhode Island	Ohio	Pennsylvania (1996)
Tennessee	Oklahoma	South Dakota (1988)
Vermont	Oregon	Texas (1985)
Washington	South Carolina	Utah (1984)
West Virginia	Virginia	Wyoming (1985)
	Wisconsin	

Source: July 2001 survey mailed by the Maryland Health Care Commission to states identified in the national Directory of Health Planning, Policy and Regulatory Agencies, Twelfth Edition, 2001, computer files, and the AHPA's electronic bulletin board.

Note: Washington did not respond to the survey distributed by the Maryland Health Care Commission. The District of Columbia reported (printed survey) that burn services are covered by CON. Georgia reported (printed survey) that a CON is not required for burn services. Kentucky reported (electronic survey) that burn treatment services are reviewed if they involve adding beds; however, coverage was not indicated on printed survey. Maine reported (printed survey) that a CON is required for a new service or an additional to licensed beds. Missouri reported (printed survey) that a CON is required for the service if the cost of developing it exceeds either the capital cost or equipment cost expenditure minimum of \$1 million. After January 1, 2002, the service will not be subject to CON unless it requires the acquisition of major medical equipment costing more than \$1 million. Nevada (electronic survey) reported that the CON program does not review specialized services, unless they involve construction of a new health facility in a rural county at a cost of over \$2 million. New Hampshire reported (electronic survey) that a new service provision and threshold may result in coverage of these services. Rhode Island reported (electronic survey) that a CON is required for tertiary care services regardless of cost; NICU and organ transplant services are defined as tertiary care services. Rhode Island reported (printed survey) that burn services are reviewable as a new service if annual operating costs exceed \$750,000. Tennessee reported (printed survey) that burn care services are regulated. Vermont regulates burn care services if they are new services with annual operating expenses above \$300,000.

V. ALTERNATIVE REGULATORY STRATEGIES: AN EXAMINATION OF CERTIFICATE OF NEED POLICY OPTIONS

The options discussed in this section represent alternative strategies governing oversight of organ transplant surgery, neonatal intensive care services, and burn care services in Maryland, all currently regulated by the Commission through the Certificate of Need program. The fundamental attribute of these specialized hospital services is their high cost and high degree of clinical complexity, and the relationship between volume of procedures and good outcomes. Consequently, Staff presents a common framework of alternative policy options for State government's oversight of these programs.

As with its other working papers in the service-specific, two-year study of the CON program, these options range, in their degree of involvement by the Commission, from the present role of CON regulation, to an intensified scrutiny and additional sanctions for non-compliance with the terms of original CON approval, to three options that remove the CON requirement. The options below, singly or in combination, suggest potential alternative strategies that could be considered in relation to the larger issue of how Maryland should regulate organ transplant surgery, neonatal intensive care services, and burn care services. As with the options presented by the staff Working Papers during Phase I, and those presented thus far during Phase II, this is not an exhaustive list of options. The Commission anticipates that other options and ideas will be generated through the public comment process.

A. Option 1 – Maintain Existing Certificate of Need Program Regulation

Under Maryland law since 1988, the establishment of a new organ transplant service, NICU service, or burn care service requires Certificate of Need approval. The Commission's decision on a given application is based on its review of a proposed project's consistency with the State Health Plan's review standards and regional need projections, and the general CON review criteria. Under this option, the CON review requirement would be maintained for new organ transplant surgery, neonatal intensive care services, and burn care services in current law and regulation. No hospital has applied, since the 1988 imposition of the CON requirement, to establish a second burn treatment center, so there is no State Health Plan section dealing with that service, as there are for both organ transplant and neonatal intensive care units.

Since these specialized services are all provided by hospitals, the statute enacted in 1999 as part of HB 994 applies to any proposal to close these services. In jurisdictions with three or more hospitals -- Baltimore City and Baltimore, Montgomery, and Prince George's Counties -- hospitals may close any of these services after submitting a written notice to the Commission 45 days before the intended closure, and holding a public informational hearing in the affected area at least 30 days before the service is to close. In those counties with one or two hospitals, however, the requirement to obtain an exemption from CON review, by Commission action, still applies. Still reviewed within 45 days, the CON exemption requires the Commission to find that the proposed closing is "not inconsistent with" the State Health Plan, will result in a more efficient and effective delivery of health care services, and is in the public interest.

Maintaining the CON requirement for new programs in these specialized services – while reviewing them against specific State Health Plan standards, as appropriate, and tailoring the means of demonstrating need for each service – helps to ensure the level of regionalization needed to promote higher volumes in each program. A strong consensus exists that higher volumes translate, in these services, into the kind of experience required to develop the highest level of skill and the best outcomes. An additional feature of the existing CON program is found in both the current State Health Plan for cardiac surgery, and the Plan chapter on organ transplant surgery: the authority for the Commission to act to withdraw the authority to operate the specified program, if the terms of the original CON approval – particularly with respect to target volumes of cases – are not met.⁶⁶

B. Option 2 – Strengthen CON Regulation

Two measures would comprise the strengthened CON regulation contemplated by this option. First, as with many other medical services examined during this CON study, the requirement – that existed in law before 1999 – for all hospitals to obtain an exemption from CON review, through action by the Commission within 45 days of receiving a written notice of the intent to close the service.

Another means by which the CON regulation of these specialized services might be strengthened is by imposing certain administrative penalties for the failure of a CON-approved and operating specialized hospital service to meet the conditions of its approval. Some mechanisms of this nature used in other states include the publication in widely-circulated newspapers or government journals of violations of the terms of CON approval, with regard to exceptionally low volumes or poor outcomes. Another measure applied in some states is the imposition of civil money penalties to non-performing programs. These measures would be undertaken prior to the final action, to withdraw the CON-granted authority to operate the specific program. In current CON regulations, an unimplemented CON may be withdrawn for the causes outlined, but such a withdrawal requires an evidentiary hearing and then action by the full Commission. Presumably, a similar level of administrative procedure would be followed, in a withdrawal of the authority to operate a previously-approved program.

C. Option 3 – Modify CON Oversight

This option would remove the CON requirements relating to either market entry or exit and quality for these three specialized services, and substitute a more intensive ongoing scrutiny of the quality of programs for organ transplant surgery, neonatal intensive care, or burn treatment. Instead of restricting the establishment or the closure of new programs of the three specialized acute care services discussed in this paper, this option would involve the creation, by the Department's Office of Health Care Quality, of a separate State licensure or certification program for each of the three services, and the requirement in law that a program obtain this document before beginning to operate the service in question.

⁶⁶ In its recommendation to the Commission on the working paper on cardiac surgery during Phase 1 of the CON study, Staff noted its intent to examine the appropriateness and the administrative logistics of applying the withdrawal-of-authority action to other medical services regulated under the CON program.

Alternatively, OHCQ could take the same approach it has historically applied to acute care hospitals as a whole and comprehensive and specialized inpatient rehabilitation services in particular, and issue a State license or certification through a “deeming” process, if the service obtains the accreditation or designation of a specified authority in the field. The State Health Plan currently requires that a proposed new neonatal intensive care unit comply with the “essential requirements for its level of perinatal program, as defined in the Maryland Perinatal System Standards.”⁶⁷ Within the category of organ transplant surgery programs in the State Health Plan, a proposed new hematopoietic stem cell transplant program “shall demonstrate its ability to meet accreditation requirements of the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT), shall qualify and apply for accreditation within three years of opening, and shall be FAHCT-accredited.”⁶⁸

This approach does not act to ensure either that proposed new services are needed or that they meet other standards related to financial solvency, geographic accessibility, and cost-effectiveness, as does CON regulation. Nor does this option require that hospitals proposing to close previously-approved and operating programs provide public notice, and in some cases undergo a Staff analysis to evaluate the impact of the closure, as required by current statute regarding the closure of hospital services. This option does not limit the number of new programs, on the front side, to ensure existing programs attain an appropriate volume to develop experience and skill and good outcomes before a new program can be considered. It takes a different approach, by requiring what may be a proxy for those factors weighed by CON: the ability to gain an accreditation or designation before beginning to operate -- or within a specified time, once operating -- and presumes that the ability to get and keep this accreditation or designation will support good programs, and winnow out under-performing ones.

D. Option 4 - Deregulate Organ Transplant Surgery, NICU, and Burn Services; Create Data Reporting Model

Another option for organ transplant surgery, neonatal intensive health care, and burn services involves replacing the CON program's requirements governing market entry and exit and quality with a program of mandatory data collection and reporting, to encourage quality in these programs through published information aimed at consumers, providers, or both. These reports could be prepared in the context of the Hospital Report Card under development by the Commission, or could be the focus of separate, smaller reports. The report card model of performance reporting and improvement is intended to collect and interpret information on how providers rate in those measures of best practices chosen as markers of quality, to help guide the health care decisions facing people who may require the services. Performance reports also provide benchmarks against which providers can measure themselves, and seek to improve quality in any areas found deficient. The disadvantage of this substitution for CON, or a similar process that assesses and restricts the number of programs in very specialized services, is that it does not address the linkage between larger volumes and higher quality, and may foster the

⁶⁷ COMAR 10.24.18, page 27, Policy 1.0. These standards were also adopted, effective March 24, 1997, by the Maryland Institute for Emergency Services Systems (MIEMSS), “as regulations to designate perinatal referral centers in Maryland and certain perinatal or neonatal referral centers in other states.”

⁶⁸ COMAR 10.24.15C(3)(f).

development of more, smaller programs, before poor outcomes can lead to poor showings on subsequent report cards, and result in some programs being sanctioned or closed.

E. Option 5 - Deregulate Organ Transplant Surgery, NICU, and Burn Services from CON Review

This option would remove the requirement for Certificate of Need review and approval for the establishment or expansion of new organ transplant surgery programs, neonatal intensive care units, or burn treatment programs, as well as any level of administrative review for the closure of an existing and operating program. It would defer to the existing authority and rules of the state health department and its licensing agency, which largely are encompassed within the overall “deeming” process of the State’s licensure of the acute general hospital that offers each individual program. Removing CON from these programs would not affect whether the programs seek voluntary accreditation or designation from a related State agency (such as the Kidney Commission, for kidney transplant programs) or an appropriate private authority, such as FAHCT for hematopoietic stem cell transplant programs. Removing the CON requirement would also not affect the authority of HSCRC to establish rates for neonatal intensive and burn care (but, like cardiac, not organ transplant surgery specifically) for each of these services, if a hospital proposes a new service, and must substantiate its expected volumes of procedures.

Table 42, following in Part VI, summarizes these policy options, as a common framework applicable to all three specialized services discussed in this Working Paper.

VII. SUMMARY

Since the enactment of a 1988 statutory provision that added four specialized hospital services to the medical services regulated by the former Health Resources Planning Commission, open heart surgery, organ transplant surgery, burn and neonatal intensive care services have required a Certificate of Need to establish in Maryland.⁶⁹ The Commission is explicitly empowered by statute to determine which health care services should be allocated on a regional basis. What identifies a specialized service is its high cost and high degree of clinical complexity, and the resulting linkage between the volume of services provided and the development of sufficient experience and skill to ensure good outcomes. The high-risk, resource-intensive nature of all four of these services suggests that a common approach to alternative options is appropriate. The following table illustrates these policy options for the future of Certificate of Need regulation of the specialized services that have been discussed in this working paper.

⁶⁹ As noted above, Staff issued its working paper on Cardiac Surgery during the first year of the Commission's study of the Certificate of Need program, and the Commission conveyed to the General Assembly its recommendation that CON regulation of this service be continued in the *Phase I Final Report* referenced above.

Table 42
Summary of Regulatory Options for Organ Transplant Surgery, NICU, and Burn Services

Options	Level of Government Oversight	Description	Administrative Tool
A. Option 1 Maintain Existing CON Regulation	No change in government oversight	Market Entry by CON; Market Exit by Notice (in counties with 3/+ hospitals) or CON exemption (in those with one or two hospitals) CON standards shall address the availability, accessibility, cost, and quality of health care.	Commission Action: <ul style="list-style-type: none"> • CON for new or expanded service • Notice or CON exemption to close service • Withdrawal of CON authority if conditions of approval not complied with (organ transplant)
B. Option 2 Strengthen CON Regulation	Increase government oversight	Market Entry by CON; Market Exit by CON exemption for all hospitals providing the service; Public notice and/or monetary penalty for violating terms of approval	Commission Action: <ul style="list-style-type: none"> • Require CON exemption to close specialized service for all hospitals; • Establish public notice or monetary penalty for failure to comply with terms of approval
C. Option 3 Deregulate from CON, Increase Quality Oversight by OHCQ	Change government oversight	No barrier to Market Entry or Exit; creation of separate licensure, or OHCQ deeming of mandatory accreditation	Commission Action: <ul style="list-style-type: none"> • May still plan for, survey use of these services; • Status of license or deeming becomes quality enforcement tool
D. Option 4 Deregulate from CON, Create Data Reporting Model	Change Government Oversight	No barrier to Market Entry or Exit; creation of specific area of hospital report card for specialized services	Commission Action: <ul style="list-style-type: none"> • Collection and analysis of use and outcomes data; • Performance measured in specific part of MHCC Hospital Report Card
E. Option 5 Deregulate Specialized Services from CON Review	Change Government Oversight	No barrier to Market Entry or Exit	Commission Action: <ul style="list-style-type: none"> • Remove CON requirement, with no additional oversight from other State or accreditation agencies; remain subject to any existing accreditation rules and to HSCRC rate-setting authority

Source: Maryland Health Care Commission